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EDITORIAL
World Association for Medical Law


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INTRODUCTION

COVID-19 has changed the way we do business. It is not just on a personal 1-on-1 basis, but it has impacted families, nations and international interactions. The World Association for Medical Law (WAML) usually holds its annual World Congress on Medical Law (WCML) at predetermined locations, which attract experts in health law, legal medicine, bioethics, to congregate in that city, to share ideas, generate contacts, foster research, encourage younger scholars and to cross-pollenate concepts that may later germinate into international collaboration. The year 2020 has seen the COVID Pandemic cause postponement of the summer Olympics but, much more importantly, it has also forced the WAML to cancel its 2020 WCML, in Toronto, Canada, delay elections of WAML office bearers and cause consternation for the editor-in-chief of the WAML sponsored journal, *Medicine and Law*.

The preparation for this issue of the Journal has proven to be a demanding process, causing loss of sleep. Acknowledging that the June issue of Medicine and Law could not proceed, along its normal processing lines, due to the COVID-19 Pandemic, it was decided to dedicate this issue of the Journal to the Pandemic. The last few years have seen the June issue of the Journal be devoted to publishing a limited number of papers, which were complemented by the publication of all the accepted abstracts for the August WCML. Even though there are already accepted abstracts for the Toronto WCML, it appears futile to publish these, in the absence of there being a forum in which they would be presented. Should they be retained until next year’s WCML, in
Istanbul, there remains next year’s June issue of the Journal in which they will be published. This created a void for the June issue of the Journal.

To ensure sufficient material was made available, all Governors, on the Board of Governor’s (BoG) of the WAML, were asked to contribute an analysis of the Pandemic within their jurisdiction. They were given a very limited timeframe and advised that each paper would still be critically refereed and had to satisfy academic standard to be included within the Journal. Each Governor was asked to summarise the local experience of COVID-19 with the aim of publishing these as a mid 2020 time capsule to reflect the Pandemic as of May 2020. At the time of preparing this Editorial, there was sufficient acceptance of invitations to allow a modicum of confidence that the Journal would have ample material to reflect the wide local experiences for this collective overview. It is accepted that this will be far from an absolute and complete picture but it holds the potential to: offer food for thought; demonstrate how different countries have adopted alternative strategies and generate sufficient material to serve as a resource that others may employ when faced with future Pandemics. Manipulating the future is predicated by learning from the past; history should provide the foundation for better planning and, with improved planning, should achieve enhanced outcome.

Any paper that was rejected by a referee was returned to the relevant Governor to allow revision to ensure that standards were maintained. Status, within the WAML, was not a ticket to acceptance. If again rejected, by the same referee, the paper was sent to a further referee to guarantee fairness. To ensure that, as editor-in-chief, no favouritism was offered, my own contribution was purposefully sent to the referee who was the first to reject a submission by one of the Governors, thereby guaranteeing that all inclusions were beyond reproach. It follows that if a jurisdiction, of any of the Governors, on the BoG, does not appear within this issue of the Journal, it is because either they did not submit a paper or they failed to pass muster, even after various offers to allow revision to achieve the required standard. This explanation is offered to ensure that no-one can malign the process employed and to confirm that all papers were treated with equal respect and expectation.

I would like to thank the many reviewers who gave selflessly their time, often on numerous papers. One such referee, who deserves special recognition, is Andre Pereira, who was pivotal to ensure that papers were assessed in a timely fashion, at times within hours, rather than days. One situation that also demands commentary is the submission from China. Within days of the deadline, for the submission of drafts of jurisdictional commentary, the Chinese representative
on the BoG, relinquished his appointment. This left a void in this overview of the COVID Pandemic, which appears to have started in Wuhan, in China. There was a great difficulty to find a Chinese representative, prepared to provide any form of statement, within the time limits. Gratitude is expressed to Prof. Sha, who, acknowledging potential significant constraints, was willing to address the void. Gratitude must also be extended to the administrative team who worked tirelessly, behind the scenes, to ensure that this issue of the Journal, *Medicine and Law*, satisfied accepted standards and was produced on time.

**THE PANDEMIC**

As of 17th May 2020, there have been 4,534,731 confirmed cases of COVID-19 reported to the World Health Organisations (WHO), with 6.8% death rate (307,537 deaths) (1). Rounding up, this equates to: almost 2 million cases in the Americas; similar numbers for Europe; approximately 340,000 in the Eastern Mediterranean; approximately 170,000 in the Western Pacific; approximately 140,000 in South-East Asia; and approximately 60,000 in Africa (1). Obviously this number of reported cases is predicated by the sincerity and integrity of those collecting the data and reporting same to the WHO and the methodology adopted to delineate the statistics and their voracity. The impact of co-morbidities and other confounding variables needs to be delineated before these figures can be accepted as genuine and it is reasonable to assume that the figures, quoted by the WHO, represent an under-reporting of the true and accurate account at any point in time. What is not clear is whether the deaths were as a result of COVID-19 or whether COVID-19 was a confounding variable for deaths associated with it.

The first cluster of the current Coronavirus infection was initially reported on 31st December 2019, when the WHO China Country Office was informed and the Chinese authorities identified a new strain of Coronavirus (novel Coronavirus, nCoV), isolated on 7th January 2020 (2). The Wuhan Municipal Health Commission, in China, reported a cluster of cases of pneumonia in Wuhan, Hubei Province, and the novel Coronavirus was identified as the causative agent. By 10th January 2020, the WHO issued a comprehensive package of technical guidance with advice to all countries on how to detect, test and manage potential cases. Based on past experience with Severe Acute Respiratory Syndrome (SARS), in 2003, and Middle East Respiratory Syndrome (MERS), in 2012, the advice was disseminated (3). On 12th January 2020, China publicly shared the genetic sequence of COVID-19 and the first case, outside China, was confirmed in Thailand, on 13th January 2020 (3). By 22nd January 2020, human-to-human transmission, in Wuhan, was officially recorded (3). Since that time, the spread of COVID-19 has become a worldwide
Pandemic, affecting the globe with resultant massive health and economic consequences with lockdowns and isolation imposed around the world.

Five months later, it is impossible to accurately predict what the full extent of the impact will be. This impact will extend far beyond just the better understanding of infectious diseases. It is expected that the lessons learnt will directly influence future management of pandemics, with: possible more rapid restriction of international travel; more focused attention to cluster isolation and management; greater emphasis upon vulnerable people, such as the elderly or the immuno-compromised; and greater preparedness for medical institutions to cope with such simple considerations, such as personal protective equipment. The epidemiological weaponry should be more reactive and, should Australia’s push for proper, in-depth, independent and transparent full scientific investigation, into the origins of the Pandemic, reach fruition, recognising that it has unanimous WHO support, without unwarranted external political pressure, it is hoped that these lessons learnt will save far more lives, into the future, than were lost to the current Pandemic.

Other considerations may include the realisation of an industrial revolution with: far greater emphasis on technology; working remotely; potential advances with artificial intelligence; changes in job requirements; modification of expected job skills; reduction of the workforce; and possibly even the constriction of the accepted working week. There has emerged a new appreciation of frontline medical personnel and it is even possible that the heroes of the future will be physicians and scientists, rather than chefs and football players. Economies may change forever, as may working environments. Virtual meetings may replace in-person attendance and such conferencing applications, such as Zoom, may reduce the number of international gatherings and help shrink the world as we know it.

Interpersonal relationships may have either strengthened or fractured as a result of lockdowns and isolation. Added to this, the emotional roller-coaster of job losses, reliance on Government support, people taking jobs they would otherwise not have contemplated, such as airline pilots stacking supermarket shelves, at night, will have impact on the very fabric of society. There may well be a baby boom 9 months after the home isolation. People, whose self-esteem has been shattered, may require additional psychiatric and medical support that has nothing to do with the infection. The rate of suicide may escalate enormously, as may the rate of domestic violence.
So many issues may emerge and evolve, as a consequence of the COVID Pandemic. This time capsule, as provided within the pages of this June issue of *Medicine and Law*, will serve as a comparator of where we have been, up until May 2020, and may provide a yardstick against which to measure future performance and demonstrate how we travelled along that route.

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AUSTRALIA
THE CORONAVIRUS (COVID-19) PANDEMIC IN AUSTRALIA – HISTORY AND POTENTIAL LESSONS

Roy G. Beran

Abstract: This paper maps out the Australian experience with COVID-19 infection from late January 2020, when the first cases appeared in passengers travelling from Wuhan, Guandong, China, through to mid May 2020, at the time of preparing the paper. It outlines the evolution of cases from 9 cases at the end of January to almost 7,000 cases by mid-May, of which 90% had recovered, 0.24% were in Intensive Care, 0.7% were in hospital and more than 900,000 tests had been performed.

The paper maps out the Government’s response to COVID-19, the restrictions imposed and the economic stimulus provided, equating to 16.4% of Growth Domestic Product. It also identified the fines to be imposed upon those who ignored the restrictions.

By mid-May the emphasis was not on “shutdowns” and restrictions but on a tempered and rational relaxation thereof with an aim to reinvigorate the economy.

On 19th March, the Ruby Princess Cruise Ship docked in Sydney, creating the single greatest progenitor of positive cases and deaths associated with coronavirus in Australia, which ultimately resulted in police investigation and a Royal Commission. Other clusters were noted such as Anglicare Newmarch House Aged Care Facility, which also led to 18 deaths due to Coronavirus and together with the Ruby Princess accounted for 40 of the 45 deaths in New South Wales (NSW). The paper also identified other clusters, such as 88 cases associated with Cedar Meats Abattoir in Victoria and the closure of North West Regional Hospital and North West Private hospital in Tasmania.
Not everyone respected the lockdown laws and the paper includes some high profile individuals, identified as having broken the rules and incurred heavy penalties, including a NSW Cabinet Minister, who was fined $1,000 AUD plus losing his State Government Cabinet position due to contravention of the Public Health Act. There were 4,500 Australians fined a minimum of $1,000 AUD for breaches of social distancing rules.

By mid May 2020, it was apparent that there were definite lessons to be learnt from the Coronavirus Pandemic and the paper maps out some of these while also pointing out that such lessons will continue to emerge from the Pandemic and may well alter the approach to Pandemics into the future.

**Keywords:** Coronavirus; COVID-19; Pandemic; Australian Experience; Lessons Learnt

**BACKGROUND**

The first case of novel Coronavirus (2019-nCoV) [COVID-19] was reported in Australia on 25th January 2020 (1), and was confirmed by the Victorian (VIC) Health Authorities. The information was conveyed to the World Health Organisation (WHO) and was related to a man who travelled to Melbourne from Wuhan, Guandong, China, on 19th January 2020 (1). Three other people, also from Wuhan, tested positive in Sydney, New South Wales (NSW) on the same day (2).

At the time, the Federal Minister of Health, Greg Hunt, outlined a swift response and capacity for testing. The Australian Chief Medical Officer, Professor (Prof) Brendan Murphy indicated, “… Victoria has followed strict protocols, including isolating the affected person…” (1). Overnight, the Department of Foreign Affairs and Trade (DFAT) raised travel alerts from Wuhan and Hubei Province, in China, to “…level 4 - do not travel…” and issued a Smart Traveller Bulletin on the virus outbreak, but its advice for China, as a whole, did not change (1).

By this stage, Chinese authorities had stopped all traffic from Hubei Province and the Australian Government released a statement that “… all passengers on flights from other parts of China will be met and provided information on arrival…” (1). Concurrently, information was posted at all entry points into Australia for passengers with symptoms on arrival or who had developed
symptoms (1). The same release also stated (1), “… Human Coronavirus with Pandemic potential is now a Listed Human Disease under the Biosecurity Act 2015, enabling the use of enforced border measures….” (1).

At this time, Prof Murphy released an ‘Alert’ statement and advised the States and Territories of the risks and relied on an ‘honour system’ for people with symptoms, on arrival to Australia, to notify the airline involved or a bio-security officer, upon disembarking (1). If symptoms developed within the week of their arrival, they were to attend their local practitioner and, if they had arrived from Wuhan, they should “… call ahead to ensure others aren’t put at risk…” (1).

By the end of January 2020, there were 9 cases of COVID-19 infection in Australia (3) and foreign nationals, returning to Australia from China, had to spend 2 weeks in a third country, before being allowed to enter Australia.

By the end of February, Prof Ian McKay, a virologist from the University of Queensland, reported, “… we are probably heading for that Pandemic even if the WHO does not want to call it that yet…” (4). By this time, deaths had been reported outside China, including Iran, Italy and South Korea (4). Prof McKay advised people to ensure they had significant “… medication and essential foods, such as canned foods, some pasta or food that can give us fibre, carbohydrate and protein for 2 weeks, if things were to interrupt the supply chain for food…” (4). It was, more likely than not, comments, such as these, which sparked a rush on toilet paper, hand sanitiser, flour, rice, pasta, paper towels and caused the supermarkets and grocery stores to limit supply to customers, such that they could only take 1 unit of some products and 2 units of others. This occurred despite Prof McKay counselling against panic buying and hoarding (4).

By the end of February 2020, the Federal Government outlined some of its Pandemic responses, such as: cancelling large gatherings; people working from home; and boosting the capabilities of hospitals (4). The message was that the State and Territory Governments were responsible for: public health responses; contact tracing; distribution of antiviral drugs; social distancing (including closing schools and work places, quarantining people, cancelling events and possibly shutting down public transport); implementing infection control guidelines; and protecting people in aged care facilities and institutions.

By mid March, schools, across Australia, were preparing for mass closures (5) after the Prime Minister, Mr Scott Morrison, announced the ban on gatherings
of more than 500 people (5). The Australian Medical Association (AMA) urged Governments to consider closing educational facilities to limit the spread of the virus (5). Plans were being developed for remote teaching and remote learning. The Federal Government developed a poster that could be displayed in businesses that had to be closed due to the COVID-19 Pandemic (6). Also by mid-March, there was a commitment to social distancing, set at 1.5 metres in Australia, with commentary that some may need to remain in place for 6 months, rather than just a short period of one month (7).

The approach to school closures was not uniform in Australia, such that NSW kept schools open until the school holidays in April (coinciding with the Easter break) while in VIC schools were shut earlier, although the school holidays were also scheduled to start earlier in that state (8). This was in direct contradiction to the announcements from the Australian Health Protection Principle Committee (AHPPC), which advocated that schools should remain open, for the duration of the Pandemic. This did not happen, although by May 2020, there was a gradual return to school with NSW initially allowing 1 day per week from the beginning of May. Some private schools in NSW opened for full-time learning while, in some States such as VIC, the public schools remained essentially shut.

By the end of March 2020, there was a forced cracked down resulting in the closure of pubs, clubs, churches and indoor sporting venues (9). The Prime Minister stated that this was mandated because of a failure to follow social distancing and he warned that this could be in place for up to 6 months. At this time, VIC, NSW and the Australian Capital Territory (ACT) moved to shut down all non-essential services within 2 days while South Australia (SA) and Western Australia (WA) closed their borders to interstate travellers, insisting on mandatory 2 weeks isolation for those crossing their borders (9). Beaches, such as Bondi Beach, had to be closed because of a failure to socially isolate.

On 12th March 2020, the Prime Minister announced a $17.6 billion Australian Dollars (AUD) economic plan to keep Australians in jobs, keep businesses in business and to support households (10). There were 4 parts to this package, namely: supporting business investment; providing cash flow for small to medium-sized businesses, keeping their employees in jobs; targeting support for those most affected; and household stimulus payments to benefit the wider economy. The actual breakdown of the stimulus is beyond the scope of this review. This was expanded to a total of $189 billion AUD (including the $17.6 billion AUD), as a second phase economic plan, equating to a 9.7% of Gross Domestic Product (GDP), and representing an “… unprecedented action to strengthen the safety net…” (11).
By 15th March 2020, Australia had 250 cases of Coronavirus infection, quarantine rules were tightened, such that all international arrivals had to self-isolate for 2 weeks (unless they were airline or maritime crew) or transitioning to Pacific Islands \(^{(12)}\). These rules were to be enforced by State and Territory Governments. On 18th March, 50\% of VIC school children did not attend school; travel advice to the whole world was upgraded to a ‘level 4 - do not travel’; domestic travel was still allowed; gatherings could not exceed 100 people; schools, while open, could not conduct assembly; only 2 people could visit aged care facilities (not including anyone recently returning from overseas or with respiratory symptoms or aged < 16 years) \(^{(12)}\).

March 19th, witnessed a monumental blunder in Australia’s management of the Coronavirus and is currently the subject of a Royal Commission, based on the arrival of the Ruby Princess Cruise Ship in Sydney, NSW \(^{(12)}\). Within 5 weeks of disembarkation, of 2,700 passengers, at 6 am on 19th March 2020, 662 tested positive to COVID-19 and 21 had died \(^{(12)}\). That same day, Australian borders were closed to non-citizens and permanent residents and Australians overseas were urged to return home \(^{(12)}\). The Reserve Bank announced a $105 billion AUD boost to the economy and their interest cash rate was cut to 0.25\% \(^{(12)}\). On 20th March, indoor gatherings were restricted to 4 m\(^2\) per person, limiting viability of event centres \(^{(12)}\).

On Sunday, 22nd March 2020, the ‘Job Seeker’ payment, for unemployed people, was doubled to $1,115.70 AUD minimum base rate and the ‘Support Payment’ of $550 AUD per fortnight \(^{(12)}\). Sole traders and those eligible for welfare could draw down $10,000 AUD from their Superannuation Funds for both the current financial year (finishing at the end of June 2020) and the next financial year (starting in July 2020) \(^{(12)}\).

Because of excessive numbers on Bondi Beach, the National Cabinet (consisting of the Prime Minister and Heads of all States and Territories) determined that from Monday, 23rd March 2020, all pubs, clubs, cafes, restaurants (excluding takeaway foods), gymnasium, indoor sporting venues, cinemas, casinos, nightclubs and entertainment venues would be shut and, despite schools being advised to remain open, online education was advocated \(^{(12)}\). Tuesday, 24th March, witnessed further extension with the closure of auction houses, real estate auctions, food courts in shopping centres, amusement parks, play centres, beauty parlours, tattoo parlours and places offering haircuts requiring > 30 minutes to perform. The haircut time was lifted 2 days later \(^{(12)}\). Outdoor gatherings were restricted to: 10 people per funeral; 5 people for weddings, namely the bridal couple, celebrant and 2 witnesses; Australians had to stay home unless for essential purpose, such
as work. Domestic travel to WA, SA and Northern Territory (NT) mandated 14 days self-isolation and Queensland (QLD) followed 2 days later \(^{(12)}\). International travel was banned. The following day all non-urgent surgery was suspended \(^{(12)}\).

By 28th March 2020, the Australian tally of COVID-infected people, was more than 3,000, having doubled within 2 days, and all international travellers were mandatorily isolated for 14 days quarantine in nominated hotels and supervised, including use of the Armed Forces, to enforce restrictions \(^{(12)}\).

By 29th March, gatherings were restricted to 2 people (excluding those within the family living together) including exercising together and socially isolating \(^{(12)}\). Those aged 70+ were advised to self-isolate, as were those with chronic disease or co-morbidities, older than 60 years, or indigenous people aged 50 or more years. There was imposed a moratorium on evictions from both commercial and residential tenancies for a period of 6 months \(^{(12)}\). By this time there appeared to be a flattening of the growth curve, from 35% to 15%, with 208,000 tests having been carried out and 3,898 confirmed cases, \(^{(12)}\) 98% of these tests were negative.

By Monday, 30th March 2020, the Government announced a $130 billion AUD wage subsidy package, called ‘Job Keeper’, providing eligible employees with $1,500 AUD per fortnight, paid to the employer, to be passed in full to the eligible employees if the employer could substantiate a 30% loss of income during the period of the COVID-19 Pandemic \(^{(12)}\). This brought the economic stimulus to 16.4% of GDP \(^{(12)}\). This was also the first day when fines were issued by both the QLD and VIC State Governments for breaches of social distancing laws \(^{(12)}\) with on-the-spot fines of ≥ $1,000 AUD for breaches of strict stay-at-home rules, being applied by the States and Territories \(^{(12)}\).

The Police in NSW announced a criminal investigation into the Ruby Princess disembarkation on Sunday, 5th April 2020, by which stage 652 of the 5,687 cases and 11 of the 34 deaths in Australia were directly linked to that ship \(^{(12)}\). By early April, people were querying the possibility of reduced ‘lockdown’ restrictions due to economic pressures \(^{(12)}\). A cluster of Coronavirus outbreak occurred in Northern Tasmania (TAS), reported on 12th April, which resulted in the closure of 2 hospitals and 1,000 health workers and their 4,000 co-habitors experiencing enforced isolation for 2 weeks \(^{(12)}\). This traced back to a passenger from the Ruby Princess Cruise Ship \(^{(12)}\).
There was developed and publicised an application (App) for mobile phones that were fitted with ‘Blue Tooth’ connectivity to trace and track COVID-19 contacts. By Monday, 20th April 2020, WA, QLD, SA and NT reported no new cases of Coronavirus, despite wide testing (12). On that day, the total national number of new cases was 26, Australia-wide, with the average daily growth rate < 1%, approximately 70% of the 6,613 cases had recovered and approximately 434,000 tests had been completed (12). This resulted in a lifting of the ban of non-urgent elective surgery on 27th April 2020 (12).

On 26th April, the COVID-Safe App was released to the public with stringent privacy regulations to identify any contact with a COVID positive person lasting > 15 minutes (12). The information was protected and could only be accessed by State Health Authorities and was automatically deleted after 21 days. Downloading of the App was voluntary but the lifting of restrictions were tied to the number of such downloads (12).

On 28th April, the lockdown was being relaxed, allowing visits to family and friends within States, such as WA allowing gatherings of 10 people and wider access to recreational activities, such as hiking, boating or picnics (12). On the same day it was announced that further people died from Coronavirus at the Aged Care Facility, Newmarch House in a 24-hour period (12). By 1st May 2020, the ACT had no new cases and restrictions were further relaxed with the emphasis looking towards restarting the economy (12). NSW stated it was to start relaxation of the severe restrictions on 15th May, with further relaxation dependent upon the tracking of the Pandemic.

CURRENT STATISTICS

At the time of preparing this report, Australia had recorded a total of 6,975 cases of COVID-19 affected individuals with 98 deaths, 6,271 recovered, 17 critical in Intensive Care, and 50 admitted to hospital. The number of tests for the virus was 909,025 of which 0.8% were positive (13). This translated to no new cases, within the last 24-hours, in ACT, NT, QLD, SA, TAS and WA with 6 in NSW and 7 in VIC (a total of 13 new cases Australia wide, all in the most populous States). The majority of deaths, 76 of the 98, occurred in NSW (45), VIC (18) and TAS (13), with < 10 deaths in each of the other States or Territories and none in NT (13).
WHY THE THREE STATES

There were 22 people who died who were connected with the Ruby Princess Cruise Ship, the latest being an 81 year old woman, who died on 13th March 2020 \(^{(14)}\). The ship docked in Sydney on 19th March and had been linked to almost 700 Coronavirus cases \(^{(14)}\). The facts and cause of this terrible outcome is the subject of both a Police investigation and a Royal Commission.

A nurse and 2 close contacts, all linked to the Anglicare Newmarch House Aged Care Facility, represented half of the 6 positive cases in NSW recorded on 13th May \(^{(15)}\). In mid April 2020, a staff member at Newmarch had been diagnosed COVID-19 positive and since then, 18 deaths followed due to Coronavirus outbreak at the Western Sydney Aged Care Facility, 2 of the deaths dying shortly after having been declared COVID-recovered, as previous tests had been negative \(^{(16)}\). NSW Health reported 69 cases of Coronavirus associated with Newmarch (37 residents and 32 staff) \(^{(16)}\). The staff member, thought to be at the root of this cluster, was said to have attended work while contagious but symptom-free. The combination of Ruby Princess and Newmarch House account for 40 of the 45 deaths in NSW, thereby leaving only 5 deaths not associated with either of these and demonstrating the otherwise excellent result for the most populous state in Australia.

A cluster of 88 cases of COVID infection were associated with Cedar Meats Abattoir in VIC and all 3 new cases, on 13th May, were close contacts thereof. The first case, linked to the Abattoir, was diagnosed on 2nd April with the second and third cases diagnosed on 24th and 26th April respectively, the latter diagnosed at Sunshine Hospital, having presented after a work-related accident resulting in a severed thumb \(^{(17)}\). Concurrently, 90 staff from a McDonald’s store are being tested for COVID-19 after 6 people, linked to the store, contracted the virus \(^{(17)}\).

Twenty-three cases of COVID positive infection were linked to the North West Regional Hospital and North West Private Hospital in TAS. As a consequence, 60 staff from the 2 health facilities were stood down to mitigate the risk \(^{(18)}\). Concurrent with this cluster, 3 elderly residents, all of whom were passengers on the Ruby Princess, died in TAS from Coronavirus \(^{(18)}\).

NON-COMPLIANCE AND COST

Not everyone followed the lockdown rules and one of the highest profile offenders was NSW Arts Minister, Don Harwin. He was seen visiting his weekend holiday home, on the Central Coast at Pearl Beach, in NSW, rather than his principal residence in Elizabeth Bay, in Sydney. He was fined
$1,000 AUD, resigned from his ministerial role and position on the State Government Cabinet due to the contravention of the Public Health Act (19). The Police Commissioner, Mick Fuller, said “… No individual was above the COVID-19 laws…” and Mr Harwin, while still a Parliamentarian, has paid a heavy price for his transgression, estimated to be well over $100,000 AUD after his loss of portfolio, well above and in addition to the $1,000 AUD fine and public humiliation.

A number of high profile sporting identities were also fined $1,000 AUD for breaking the rules. These included Latrell Mitchell, Joshua Addo-Carr and Tyronne Roberts-Davis (all highly paid, professional, rugby league football players), who went on a camping trip with 10 other men with 1 of the players, displaying absolute disregard, posted a “… video of the alleged trip to social media…” (20). NSW Deputy Police Commissioner, Gary Worboys, confirmed there was to be a detailed investigation into the incident (20). The players added insult to injury, claiming cultural reasons for the breach, as they were all indigenous Australians, despite their apologising for their behaviour. The governing body of the National Rugby League proposed a $50,000 AUD fine, each to Addo-Carr and Mitchell for breaching self-isolation, although 60% of the fine, plus a 1 match ban, were suspended (21). This was 5 times greater than the original fine that had been imposed on another such football player, Nathan Cleary, for breaches of social-distancing laws, although this was later increased to $30,000 AUD and a 2 match ban, once it was revealed that Cleary had been “untruthful” in his disclosures to the Code’s Integrity Unit (21).

These examples confirm that those with high profiles, who flaunted the lockdown laws and who were identified as doing so, were subject to considerable penalties. Almost 4,500 Australians were issued with fines of $1,000 AUD for breaching social distancing rules (22). VIC issued the most fines while the ACT issued none, demonstrating that the application of the penalty was not uniformly imposed (22).

**DISCUSSION**

The results of Australia’s management of the COVID-19 Pandemic look extremely reassuring, to the point that there now exists a strong impetus to move forward, relaxing the imposed restrictions on society and seeking to motivate a speedy recovery to enhance the stalled economy. This may be premature, as there are hidden factors that do justify reconsideration.
Many of the countries that have suffered much more due to the COVID-19 Pandemic, are coming out of the flu-ridden winter months, which have impacted on the Northern Hemisphere and which will have exacerbated the propensity to viral infection. Australia, being in the Southern Hemisphere, has come out of a long, hot summer and equally hot autumn, which may well have been protective against flu-like symptoms, as per the COVID infection. Conversely, the fear of COVID has seen a significant acknowledgement of the need for influenza vaccination with the Federal Government procuring record 16.5 million flu vaccines (23). At the time of writing this report, the Therapeutic Goods Administration (TGA) had already released 13.8 million vaccines (23). The death rate from influenza, in 2017, was 1,255 in Australia, which equates to a 3 month total that is 3 times that of the COVID-related deaths, thus far.

Another real benefit of the shutdown was the reduced road usage. This resulted in 60 less road-related deaths, compared to the same period last year. This and other such figures are often overlooked within the wider picture.

Experience with Coronavirus has resulted in far greater appreciation of the need for better hygiene, protecting staff in shops and commercial premises, better cleanliness everywhere with ubiquitous hand-sanitisers and other attention to detail to sterilise public transport and public places. These activities may well protect against the winter 2020 increase in influenza and may represent a positive effect of the Coronavirus Pandemic.

The greater emphasis on working from home has been suggested to potentially change the way people will work in the future, post COVID-19. This remains to be seen but it has the potential to remodel the fabric and nature of Australian society.

There are definite lessons that Australia must learn as a consequence of its experiences with the Coronavirus Pandemic. The experience with Ruby Princess and Newmarch demand greater focus on potential clusters of infection and appropriate intervention, addressed to minimise extension of these clusters of infection, may have achieved a much better outcome for the total population without the economic havoc that has resulted from the closures, job losses and interruption with private commercial activity.

Another real concern is the potential for a second wave of COVID-19 infection because the population is becoming complacent and there is a tendency to no longer respect to social distancing and enhanced hygiene considerations.
that have been practised meticulously during the COVID-19 Pandemic. It is for this reason that the government has insisted that it will not relax the impositions too rapidly and will offer measured and controlled approach to relaxation but it also recognises the unequivocal economic imperative, based on the unemployment figures for April having risen above 6%, despite a massively increased non-participation rate. The outcome thus far has been exceptionally good but only the future will tell what the true price is for the COVID-19 Pandemic. Australia has sought a detailed enquiry into the Pandemic and its origins and, as a consequence, the Chinese Government has started to impose sanctions, muting heavy tariffs on grain and barley exports and impacting on meat exports from Australia to China. At the time of preparation of this review, the full ramifications of the COVID-19 Pandemic are not fully appreciated and that may also include marked social consequences with muted increase in family break-ups and suicide that could eventuate as a result of the isolation and lockdowns that were imposed. There may also be a ‘baby-boom’ 9 months after the COVID-19 lockdowns.

It remains to be seen what will be the full legacy of the COVID Pandemic and it is hoped that the world will learn from sharing experiences.

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AZERBAIJAN
POLITICAL, SCIENTIFIC AND MANAGEMENT ASPECTS OF CORONAVIRUS PANDEMICS: CONSIDERATIONS FROM AZERBAIJAN PERSPECTIVE

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Abstract: COVID-19 has changed the world. Four billion people have been isolated for months and all international flights, events and gatherings, sports and cultural programs cancelled. The global economy has collapsed. International organizations, national and international leaders could not shade their own weaknesses and disorientation. Wrong decisions, non-justified actions and declarations were made. The media’s involvement has largely aggravated the dangers of this pandemic. This pandemic is a medical and biological problem as well as a time of learning for international communities.

Keywords: Coronavirus Pandemics; Strategies; Mortality; Media; Immunity

GENERAL OUTCOMES OF PANDEMİCS İMPACT ON THE WORLD

Four billion people have been completely or partially isolated and suffered from lock-down policies. The pandemic affected 217 countries. As for 28th of May 2020, there are more than 5.3 million confirmed infected and about 351,886 deaths in the world: 7% of those infected have died. The numbers of infected, dead and recovered continues to increase – comparatively, the

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death rate was 5.5% a month ago. The accumulation of data and worsening of the COVID mortality rate will assist in taking the appropriate steps. Though this pandemic has raised serious concerns on a global scale, it may not mean that quarantines, lock-downs and deprivation of freedoms must continue.

All international flights, events and gatherings, sport and cultural programs have been cancelled. Global events such as the Tokyo Olympics Games, World Expo and world congresses were postponed. WAML cancelled its 26th World Medical Law Congress in Toronto, Canada, scheduled for August 2020.

International and professional communities have begun to doubt the legitimacy of the WHO (World Health Organization). The WHO has failed to emphasize the early signals from China, at the end of December 2019, only announcing a global pandemic on March 11th 2020, after multiple countries implemented states of emergency.

**PANDEMICS SITUATION IN AZERBAIJAN: LOCK DOWNS AND QUARANTINE**

Like many other countries, Azerbaijan stringently followed WHO’s recommendations. It experienced panic, with a sharp increase of media cover and information from other sources that furthered the effects of the pandemic. National television channels started to repeat messages covered in the world media, with about 90% related to death, catastrophes and fatalities. The Azerbaijan population entered lock-down from 31st March till 18th of May. Government workers, medical personnel fighting COVID 19, food providers and market workers were eligible to work and be outside. The “EvdeQal” (Stay at Home) campaign allowed others a two-hour window for shopping for groceries close to their residence and appropriate medical needs, employing telemedicine/telephone consultations. The elderly were deprived of this

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right and forbidden to go outside their place of residence. The government mandated closure of all international and intranational traffic except for state needed logistics.

Though the pandemic is not over, the campaign is now coming to a halt, similar to other European countries. Why did the economy and social life have to collapse if people are currently able to return to a “normal life” despite the ongoing pandemic? The sole answer that arises is a lack of strategy in organizations. Was “EvdəQal” (“Stay at Home”) justified? Data show that Belarus’s and Sweden’s no lock-down policies did not worsen their results compared to Azerbaijan: the mortality rate in Belarus is half of that of Azerbaijan despite a higher number of infected.

**THREATENING PEOPLE TO JUSTIFY LOCK DOWNS**

Some governments used the pandemic to test deprivation of constitutional rights and learn about the public’s reactions, possibly abusing this situation for their own political interests based upon the WHO recommendations. Countries like Italy and Spain had mortality rates greater than 15% among the infected – strict lockdown policies likely may be necessary in such countries. In Russia, Turkey, Azerbaijan, Kazakhstan, Uzbekistan and other in the regional nations, where mortality rate was around 1%, the stringent quarantine mandates were dubious. The governments’ advice of threats of disease equated infection with COVID-19 to a death sentence, provoking potentially unnecessary public panic. A television appearance highlighting the non-acceptability of such an approach of “false threat” was censored and the presenter was later obstructed from public speaking.

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11 COVID-19 Worldwide Dashboard. WHO Live World Statistics. https://covid19.who.int/?gclid=Cj0KCQiwvr32BRD4ARIsAAJNiF_0r63v1uAOUI0CFpOix93FLLesYtkEIoTvNEm75LoMVV1AZyCCHbUuQaAu7QEA1Lw_wcB
There is support for the emphasis on accountability for personal hygiene, social isolation, distance on the streets, quarantine in schools and universities, closing restaurants, pubs and stadiums, to act as general rules of prevention of spread, as proposed by WHO and they must be strictly implemented\textsuperscript{15}. There is criticism of this SMS system and closing of parks, deprivation of people's rights to mobilize and travel, whether on land or in the air. People aged 65+ were imprisoned in their homes for 2 months. Daily alarming information from the media created public panic and stress that certainly had an impact on the public's mental health.

The Holy Qur'an states that every harm has a benefit and every benefit has a harm. Ayat 45 of Surat al-Baqara says, "And seek help through patience and prayer in times of trouble. While this is hard work, it is not hard for those who obey to Lord"\textsuperscript{16}. A state of calmness and logic in these unpredictable times might elucidate both the negative and positive changes that evoked.

To reassure the disoriented public, two articles were published in the Azerbaijan media titled "Coronavirus is a not pandemic, this is a war" on April 3\textsuperscript{rd} and "We are not main targets for COVID-19" on May 1\textsuperscript{st} (17,18). These received more than 150,000 views and significant positive feedback.

\textbf{CONSIDERATIONS ON POLITICAL ASPECTS OF PANDEMICS ORIGIN AND IMPACT}

Unlike previous pandemics and epidemics, COVID-19 allowed such an extensive spread to impact the global political, social and economic arenas. The French prime minister, Philippe, and other politicians called the pandemic even worse than war and occupation. Although not entirely clear, there are those who consider it to be a war started by China. Others question it to benefit some in the United States, being potentially relevant to its 2020 Presidential elections. It is also possible that other world leaders were partially aware
of this theory and took advantage of the impending pandemic, this might include the referendum in Russia or the extraordinary parliamentary elections in Azerbaijan\textsuperscript{17,18}.

There has been a realignment of relations between international powers and an interruption to international law. The pandemic may have turned a potential military war into an economic war. Oil, coal, tourism, sports, food, and travel industries have been severely affected, with all service businesses ceasing operations. Nations of the European Union and others may experience changes in values and democratic process, leading to a shift in global order. Those with strong leaders and economies may survive while those without either may fall. Some argue that complete inaction would still have led to an end of the pandemic, with a 90% survival rate.

\textbf{WAYS TO OVERCOME PANDEMICS PROBLEM}

There are two ways to overcome the pandemic:

- development of a vaccine
- herd immunity within the population

Both require time and patience: a COVID-19 vaccine is currently not available and is unlikely to be so for some months.

To develop herd immunity, a significant percentage of the population must become infected for the development of appropriate antibodies, preferably while quarantined in their homes and following guidelines on personal hygiene. Independent of this at-home quarantine, new cases will continue to occur as the incubation period is at least 2 weeks. Increasing the number of tests will increase the identification of the number of those infected. There are some positive aspects, in terms of gaining natural immunity, as 90% of those infected have already recovered.

The Stay at Home campaign (“EvdeQal”) is effective at slowing down, but not overcoming, the infection. Though the virus is highly virulent, the low mortality rates offer a positive aspect. In nations with the worse infectious

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spreads (Italy, Spain), the mortality rate did not exceed 10% (April 3rd 2020) and is now up to 16%. In countries with streamlined and effective healthcare systems, such as Germany, Israel and Turkey, this percentage was between 1.5 and 5% (April 3rd 2020). The great majority of infected people had mild symptoms and were able to recover and return quickly to a normal life. There is a direct link between mortality and the preparedness of the healthcare systems.

**RESPECT TO PSYCHOLOGICAL CONDITION OF POPULATION IS IMPORTANT**

We believe this crisis is not directed at the physical existence of humanity. It was mentioned that the main purpose of this crisis was to collapse the global economy, paralyze states through public panic and influence target political processes. States should have preventive measures and strategies to combat such theories, potentially becoming reality. As most did not, the majority of leaders were disoriented to guide the nations on the right path. The longevity of the pandemic underscores public satisfaction and sustainable yet effective strategies for public informing along with reassurance. This is a role that should be taken up by the media – globally, the media has failed and often instigated further public panic and confusion. The World Media and WHO were the main instruments in the hands of those who would benefit from triggering public fears and dissolve some of their human rights.

“Stay at Home” may be useful for short-term goals, such as preventing sudden overloads on the healthcare system. In the long-term, we must keep in mind that the guidelines reducing infectious spread are going to negatively impact the public sooner or later. States supported flash mobs and videos were not helpful in neutralizing the media’s negative effects. For weeks, since beginning of pandemic, Azerbaijan was concealing objective information, such as facts about the disease, recovery and essential guidelines. It tasked all media channels to equate coronavirus infections with death, consider to be wrong. During crises, accurate and honest communication and information exchange with the public must be further prioritized to reduce any misplaced or unnecessary fear and panic. In Azerbaijan, 90% of the media’s broadcast became negative and induced a depression of public mood and attitude. In mid-March, there was a television program being prepared in which the guest was expected to create fear and to equate the illness with death. This was contrary to the views of the speaker who felt that people should not be afraid of COVID-19. The speaker was ostracized when sharing data showing 80% of
those infected had mild symptoms and that hospitalization only occurred in 1 out of 5-6 people, with most recovering fully.19.

POLITICS & MEDIA DOMINATES OVER THE SCIENTIFIC KNOWLEDGE IN PANDEMICS MANAGEMENT

There was irony in the lack of freedom of speech in the farthest reaching media. The world awaits a vaccine, the only panacea according to the propagation of the media. Some argue that vaccination cannot be considered as a panacea and people should have a choice whether or not to receive it when it becomes available. The Azerbaijan experience has shown that broadcast companies were scripting the statements of the people they invited onto their programs.

BENEFITS THAT AZERBAIJAN HAS IN COMPARISON WITH OTHER GEOGRAPHIES

The number who recovered is not less significant than the number of deaths. The most severely hit countries have a ratio of recovered to dead as 6:1 while Azerbaijan and neighbouring nations have a ratio of 50-60:1. It is argued that the media is fundamentally wrong to deliberately equate a coronavirus infection with death, when the above statistics say otherwise. On April 3rd in Italy, there were 150 deaths and 925 who recovered and were discharged. In all nations, the number who recovered is higher than the number of deaths. 11,12,13,14,17,18,20.

A focus on positive aspects is also essential during this crisis. The number of recoveries is higher than the number of deaths in all countries. Quarantining at home will last more than 1-2 weeks so it is crucial to be aware of the public’s mentality and any changes during this time.

Though Azerbaijan has a modern healthcare system issue, the Soviet medical ideology and principles have not yet completely disappeared in health officials. Soviet medical ideology is based on state priorities rather than commerce/business. At the beginning of the pandemic, in early March, two main issues, in the healthcare system, were stressed using Facebook, ;

20 https://www.facebook.com/vugar.mammadov.52/posts/1512927702218433
- extracorporeal membrane oxygenation (ECMO) equipment must be bought.
- Access to equipment, social security and protection of health care workers, engaged to the pandemics management process, needed to be strengthened. They should be provided with regular diagnostics, good wards if they fall ill, care, and, if necessary, priority use of oxygenators and other benefits.

A week later, the country’s leadership increased the salaries of medical workers who were directly involved in the fight against the coronavirus and brought the necessary oxygenation equipment into the country.

The “EvdeQal” (“Stay at Home”) campaign may be justified to prevent a sudden overload of the healthcare system.

On April 3rd 2020, the countries most affected by the pandemic included the United States, Italy, Spain and other European countries (Belgium, UK, France, Germany, Netherlands), China, South Korea, Japan and Iran. At the time, there was no coronavirus in Turkmenistan, North Korea and Taiwan. The geographical proximity of Taiwan and China was an indicator of dissimilar impact of the pandemic. Belarus, Sweden and Mexico continued without lockdown policies. Compared to other nations, the situation in Azerbaijan was not that bad. By April 3rd, Azerbaijan had 4,000 people in quarantine, about 400 diagnosed patients, 26 recovered and discharged home and 5 deaths related to old age and other diseases. Azerbaijan Airlines ensured the return of 20,000 Azerbaijani citizens from abroad, established an operational headquarters, increased the salaries of medical workers, activated the volunteer movement, created care programs for the elderly, allocated large financial resources and supported entrepreneurs. The President and the First Vice-President set a good example by transferring their annual salary to the Coronavirus Foundation which is now 100+ millions USD$^{21,22,23,24}$.

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22 AZAL is taking special measures to prevent the spread of coronavirus. https://www.azal.az/en/article/543
MAIN SHORTAGES OF PANDEMICS MANAGEMENT IN AZERBAIJAN

Many people did not obey “EvdeQal”. Most of them went out to maintain their income. It is argued that the state’s financial supports were not given to all or in a timely fashion making the ‘lock down’ difficult for many. Thousands of people were punished by fines and hundreds were arrested.

Officials, singers, lawmakers, observers and journalists advocated for “EvdeQal” when they had no problem with income and associated basic needs for survival.

Many people in Azerbaijan earn their money through daily work outside of their homes. State financial assistance of about 105 USD/month was implemented for the unemployed, but the payments were often delayed and sometimes not forthcoming at all.

As Azerbaijanis, there are religious and cultural imperatives that run contrary to how people part with their deceased when considered through the methods outlined by the WHO or carried out elsewhere. Coronavirus deaths will increase necessitating a rethink about how corpses will be buried and how they will be sent to their final destination by their loved ones.

Another suggestion was to look at the experiences of Portugal and Ukraine, where there were no very important person’s (VIP) wards, VIP rooms or VIP quarantines. This virus should stop categorizing people as VIPs or ordinary. Those who consider themselves VIPs should understand that the others are experiencing the same or worse fates. Along with globalism, this viral

26. Who will be given once 190 AZN as unemployed? https://www.bbc.com/azeri/azerbaijan-52236554
29. Natacha Larnaud. “No chance to see their loved ones again”: Funerals in Italy have been banned, and many are being buried alone. 27 March 2020. https://www.cbsnews.com/news/italy-has-banned-funerals-now-after-coronavirus-patients-die-alone-they-are-buried-alone-too/
pandemic must help break down these artificial barriers between people to facilitate equitable allocation of rare resources. Everything needs to be people-oriented\textsuperscript{30,31}.

**MORTALITY ANALYSIS SAYS A LOT TO MAKE GOOD PROGNOSIS FOR AZERBAIJAN**

At the beginning of May, 80-87\% of all known infected people on the globe were in the United States and Western Europe: 2.6 out of 3.1 million. This provided reason to suggest that the real TARGETs are THERE. The death rate of infected people was 6-16\%: 16\% in Belgium, 14.3\% in France, 14\% in the UK, 14\% in Italy and 12\% in the Netherlands\textsuperscript{11,12,13,14}. 1.3\% of 1700+ infected people died in Azerbaijan (22 people),

- 14 people died in Singapore with 14,951 infected patients (death rate 0.09\%),
- 10 people died in Qatar with 11,921 patients (0.1\%),
- 2811 patients 8 people died in Bahrain (0.3\%),
- 0.4\% in Uzbekistan and Kuwait,
- 0.6\% in the UAE with 11,380 patients,
- 0.8\% in Saudi Arabia with 20,077 patients and
- 0.8\% in Belarus with 12,208 patients.
- 0.9\% in Russia with 93,558 patients,
- 1\% in Kazakhstan with 3,027 patients\textsuperscript{11,12,13,14,17,18}.

In Azerbaijan, the death rate was 1.3\%. In neighbouring countries, with less modern healthcare systems, the mortality rate is even better than Azerbaijan’s. It seems that one of the positive results was a consequence of the maintenance of the Soviet healthcare system.

China’s satellite territories with populations of millions have low mortality rates: in Taiwan (1.4\% of infections, 429 infections, 6 deaths), Hong Kong


\textsuperscript{31} Coronavirus provided interesting “social experiment” in Ukraine. 24 March 220. https://regnum.ru/news/2893746.html
(0.04%, 1038 patients, 4 deaths) and Singapore (14,951 patients and 14 deaths). This is an integral part of the statement on China’s role that was expressed on a Facebook page. Further analysis in the near future will reveal China’s role, if any, in this pandemic and the relevant factual events.

Azerbaijan will return to normal. With a mortality rate of 1.3%, 99% of Azerbaijan’s 10 million population will recover, even if all are infected. Another reassuring statistic is that compared to an average of 5-6 recoveries per 1 death globally, Azerbaijan’s is 56:1. The number of those who are healed is many times greater than the number of those who die. At the end of March, illness and death were equated by some of our officials, we stated that 80% of our patients will have mild symptoms and that fear is unnecessary. Most of patients were able to be treated at home under supervision. This is not an idea that was prominent in Azerbaijan and thus ignored while organizing other ways of mitigating the spread of COVID-19.

OTHER GOOD EFFECTS OF COVID 19 PANDEMICS

Even those officials who did not address the factual data now realize that it is not just the public, but those individuals, higher in societal hierarchies, who are also vulberable. The danger can affect everyone equally. Fear in moderation is essential and resulted from medical and economic factors. Some have realized that, as the Holy Qur’an states, the beautiful “gardens” they have built can be destroyed to ashes in an instant. The slogan “We are Strong Together” finds its origin here. Azerbaijan is not alone in this slogan: Russia, Turkey and other countries are undergoing the same experiences. Leaders realized that to maintain leadership, they need the support of the people.

One should acknowledge the heroism of frontline doctors and medical workers. Along with the improvement of the ecological situation in the world and easing

of military conflicts, a main point of this pandemic is global the change of attitude and an increased respect for doctors There is a big distinction between doctors’ personal commitments and an organizational structure of a healthcare system and capabilities of health authorities.36,37,38.

**IMMUNITY WILL WIN THE VIRUS, DO NOT FORGET THIS!**

It is not the quarantine, but the human immune system that will beat the virus.

Here are some of our recommendations:

- Do not be afraid of illness and disease. Protect yourself, but do not be afraid!
- Maintain your psychological comfort. Psychological stability is more important for your health and immunity than being informed. If the information broadcast by the media worries you, switch it off, and do not 12 and instead, spend the time talking on the phone with family and friends.
- Fresh air is an important condition. It is important to be protected and walk alone in the fresh air. Change the air in your home often if you can’t go out.
- Good nutrition is an important condition. Eat fruits, vegetables, onions and garlic after a good wash. Consider taking vitamin supplements.
- Remember physical activity. Walk at home or try standing for normal activities so that you are not constantly sitting or lying down. It is good to do sports or workouts at home.

Besides the negative factors brought on by COVID-19, some positive aspects have also been unveiled. The increased respect for the medical profession in society, attention to personal hygiene, the cessation of military conflicts, environmental benefits, moral changes in term of solidarity and equality....

Quoting the words of the great Oriental scientist, Ibn Sina (Avicenna)::

- “Panic itself is half the disease.
- Peace of mind is half the health.
- Patience is the beginning of healing”\textsuperscript{39}.

Let us stay calm and patient, learning lessons this pandemic brought to our common world.

\textsuperscript{39} https://m.facebook.com/davron/posts/3090144034337781
BELGIUM
HEALTHCARE LAW AND THE COVID-19 OUTBREAK IN BELGIUM

Thierry Vansweevelt* and Filip Dewallens**

Abstract: This article describes the Belgian response to the Covid-19 crisis. Several decisions were taken by the Federal government with far-reaching consequences and restrictions on liberties. These restrictions, such as the requirement for people to stay at home and the closure of shops, derogate from existing legislation and fundamental liberties (private life, freedom of association and free movement). Hospitals had to cancel all consultations, tests and non-urgent medical procedures and had to prohibit visits. This article focuses on the consequences of these measures on healthcare quality. Telemedicine and triage via telemedicine are protective measures but can also lead to diagnostic errors. Triage undertaken in hospitals and nursing homes could affect the right of equal access to healthcare. Lack of personal protective equipment and defective mouth masks could also trigger the liability of the hospital or the government. It is critically important and reassuring for healthcare providers that insurance companies have confirmed coverage for healthcare providers’ liability in these unusual circumstances.

Keywords: Covid-19; Health Law; Belgium

Introduction

In response to the Covid-19 crisis, several decisions were taken by the Belgian federal government with often far-reaching consequences and restrictions on liberties. These restrictions included the requirement for people to stay at home and the closure of shops, derogate from existing legislation and fundamental

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1 Legislation in this article was up to date as of 1 May 2020
liberties (private life, freedom of association and free movement). Hospitals had to cancel all consultations, tests and non-urgent medical procedures and prohibit visits.

1. Public Intervention Emergency Measures

a) Competent authority

Due to the complex federal Belgian state structure - which includes eight ministers responsible for public health, as well as the interior minister’s security powers - it is not obvious how decision-making can be both adequate and constitutionally compliant.

The federal government is basically the competent government to coordinate and manage any crisis and is, by default, competent when an acute pandemic is imminent. The federal government is not exclusively competent when a healthcare crisis occurs. The regional governments are generally competent for public healthcare and responsible for tackling a healthcare crisis. It is necessary to determine which particular matter is appropriate for a specific level of government to regulate. Different authorities may be competent at the same time, depending on the action (such as preventive measures, drug distribution or the practice of medicine). The regions (communities) are responsible for preventive health care, including the detection and control of infectious diseases. In 2003, the Flemish Community issued a Prevention Decree. The Flemish government can take measures to prevent harmful effects caused by biotic factors. On this basis, the Flemish government prohibited visits to residents in nursing homes and homes for the elderly from 13 March 2020. As a result of this complex and elaborate division of powers, rapid and timely decision making has not been easy. The federal and regional governments decided to delegate crisis management to new governmental bodies with overarching competence (supra nr. 7).

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2 Parl.St. Senaat 2013-14, nr. 5-2232/1, 6 en 43 and Parl.St. Senaat 2013-14, nr. 5-2232/5, 247-249.
5 Parl.St. Senaat 1979-80, nr. 434/1, 6; Parl.St. Kamer 1979-80, nr. 627/10, 52.
7 Art. 39 (and next) Flemish Decree November 21, 2003 on preventive health policy, BS February 3, 2004
The federal government’s assigned and exclusive competence regarding preventive health care is the competence to take nationwide “measures on prophylaxis”. This only concerns mandatory vaccinations. If the federal government wants to act during a health care crisis, it must invoke powers other than those relating to this narrow competence in public health. For example, the fundamental ban on leaving one’s house that was issued to the population was taken under civil protection and safety legislation. The same legislation was used to declare the federal phase of the national emergency plan. Federal economic legislation was then used to regulate the trade and distribution of various medical devices, personal protective equipment and biocides. Shortages of medicines were addressed under the Pharmaceutical Act.

b) Delegation of Powers

To deal with this fragmentation of competencies and allow swift action, a Delegation of Powers Act was declared by parliament on 27 March 2020. It gives the federal government broadly defined and prima facie unlimited powers to tackle the crisis. For a period of three months, measures can be taken to prevent the spread of the virus and to preserve public health and public order (such as providing sufficient medicines and medical devices). The government

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9 See article 5, §1, I., lid 1, 1°, a) en lid 2, 2° (BWHI) Special Law to Reform Institutions of August 8, 1980, BS August 15, 1980.
14 For example, see Royal Decree of March 24, 2020 taking special measures to combat drug shortages under the SARS-CoV-2 pandemic, BS March 24, 2020.
15 Law of March 27, 2020 authorizing the King to take measures in the fight against the spread of the coronavirus COVID-19 (II), BS March 30, 2020. Also in 2009, a Law was voted on that gave executive powers to the government in the event of a flu epidemic or pandemic: Act of October 16, 2009 granting permissions to the King in the event of a flu epidemic or pandemic, BS October 21, 2009.
can also take all necessary measures to safeguard logistic capacity (security of supply) and provide additional capacity (including requisitioning scarce resources for hospitals). The Royal Decrees implementing this Delegation of Powers Act may lift, amend or replace any existing legal provision but they have to be ratified by parliament within a period of one year.\textsuperscript{18}

The Delegation of Powers Act does not give the federal government full discretionary powers. The government must respect legal standard that guarantee minimal public freedom and the imposed restrictions must be justifiable and acceptable. Making regulatory actions very delicate - the division of powers, between federal government and the regions, should not be violated (including preventative measures).\textsuperscript{19} The regions themselves issued delegation of powers legislation in order to address matters ordinarily within their competences.\textsuperscript{20}

c) Pseudo-legislation

On 18 March 2020, all non-urgent consultations, diagnoses and procedures were postponed and visits to hospital patients were prohibited. This decision was taken by the Federal National Security Council\textsuperscript{21} and the Risk Management Group (RMG).\textsuperscript{22} Although these bodies are official public entities,\textsuperscript{23} their decisions are neither binding nor enforceable, without further legal formalization, for two reasons:

\begin{itemize}
\item 17 Parl. St. Kamer 2019-20, nr. 1104/001, 6.
\item 18 Articles 5, §2(2) and (7) (2) Act of March 27, 2020 authorizing the King to take measures in the fight against the spread of the coronavirus COVID-19 (II), BS March, 30 2020.
\item 21 The National Security Council was established by Royal Decree of January 28, 2015 establishing the National Security Council, BS January 30, 2015.
\item 22 www.info-coronavirus.be
\item 23 The Risk Assessment Group (RAG) and the Risk Management Group (RMG) were established under various protocol agreements between the federal government and the regions: See also point 4.4. annexed to the Royal Decree of January 31, 2003 laying down the emergency plan for crisis events and situations requiring coordination or management at national level, BS February 21, 2003, which includes an evaluation cell, a management cell and information cell.
\end{itemize}
1° The National Security Council is competent only for determining general intelligence and security policy and coordinating and determining the priorities of the intelligence and security services. Nowhere does it stipulate that the National Security Council can lift or amend existing legislation (in contrast to the delegated powers defined by the Delegation of Powers Act), or exclude or restrict fundamental freedoms (which is possible to a limited extent under the Delegation of Powers Act). An affirmative *a contrario* argument for that matter is that no Delegation of Powers Act would have been necessary if the decisions of the National Security Council had been binding.

2° The establishment and operational scope of the RMG is based on protocol agreements between the federal government and the regions. These protocol agreements define the structure of health care management in the event of a crisis. These protocols are necessary for policy cohesion because of the fragmented health competences of the various governments. When the RMG was set up, it was stipulated that it could take measures and decisions. These are only decisions in principle which need further implementation. The protocol agreement stipulates explicitly that the RMG’s decisions ‘may’ be further implemented and that such implementation is the responsibility of the federal government and the regions, each according to their respective competences.

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25 The most recent dates from 2018: Protocol agreement of November 5, 2018 concluded between the Federal Government and the authorities referred to in articles 128, 130 and 135 of the Constitution, establishing the generic structures for the sectoral health management of public health crises and their working methods for the application of the International Health Regulation (2005), and Decision No 1/2005 of the European Parliament and of the Council of December 22, 2008 on the implementation of the Constitution. For the first time, it is necessary to make it clear that the commission should be informed of the need for health concerns, BS December 14, 2018.
26 Article 5, §5, lid 2 Protocol Agreement.
27 Article 6, §1 Protocol Agreement. The fact that the decisions of the RMG and the National Security Council as such do not have the force of law is confirmed by the fact that some of those decisions were included in federal and state decisions. For example, the determination of the crucial sectors and essential services, the fundamental ban on the population leaving the home and the rule of social distancing, included in a Ministerial Decision of April 3, 2020 amending the ministerial decision of March 23, 2020 laying down urgent measures to limit the spread of the coronavirus COVID-19 , BS April 3, 2020.
2. Nature and Type of Measures

a) Requisitioning of health care professionals

In the case of an imminent shortage of available medical practitioners (because they are ill, deployed elsewhere or not competent), the government might consider requisitioning them. The federal government is responsible for the practice of medicine and for a minimum level of permanent medical staff. The federal government could implement a requisitioning measure which can be instigated through federal health inspectors. If there is insufficient staff, these inspectors can requisition individual medical practitioners. The federal government can generally invoke civil security legislation. This statute allows the interior minister to claim ‘persons’ in general, which includes medical practitioners. Requisitioning measures are also possible under the Delegation of Powers Act. On 29 April 2020, the government chose the latter option. The Minister of the Interior, in consultation with the Federal Minister of Health, can give an executive order to provincial governors to requisition health care professionals in order to address identified capacity problems. To date, neither such measures proved necessary because many health care professionals volunteered and trainees were employed.

b) Requisitioning of medical equipment

There is a scarcity of the protective and medical materials needed to prevent the spread of the coronavirus. Both health care professionals and a large portion of the population want to use these materials. There may also be compromised access to certain medicines and raw materials. Specific measures were taken to ensure the flow of manufacturing, distributing, sales and export of drugs and medical materials. These measures were issued under the Pharmaceutical Act and the Code of Economic Law.

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29 Article 28, §§ 2 and 3 Act of May 10, 2015 on the exercise of health care professions, coordinated on May 10, 2015, BS June 18, 2015 (hereafter Health Care Professions Act).
30 From July 1, 2021 on, the provincial governor may also, under article 25 of the Quality Act of April 22, 2019, claim participation in the permanence by the health care practitioner on his/her own initiative or at the request of the Supervisory Committee.
c) Limiting professional autonomy

The RMG decided to cancel or postpone all consultations, tests and non-urgent medical procedures. This measure was not formalized in an act or implementing decree and is neither binding nor enforceable. Under the Health Care Professions Act, doctors should not be subject to regulatory restrictions on their professional autonomy. A restriction on the choice of resources, for either diagnosis or treatment, can only be effected by a law and not by executive order.

Hospitals and their medical directors could decide to postpone the non-urgent treatment of patients on the basis of their corporate and clinical responsibility for the hospital organization. This crisis evokes a force majeure in the sense that there is an acute shortage of resources to carry out non-urgent interventions, in addition to urgent interventions, and the treatment of COVID-19 patients. Certain procedures cannot be performed without the guarantee that patients can subsequently be admitted to a post-operative intensive care unit. The scarcity
of these medical resources creates a force majeure and justifies the hospital’s intervention to optimally deploy available resources. The hospital also has to prevent the risk of infection for other patients and for the practitioners who would be involved in any non-urgent procedures. The hospital management must carefully consider the choice of resources that may or may not be used. The Health Care Professions Act prohibits the obstruction of the normal practice of medicine and that prohibition also applies to hospitals.

d) Limiting visit

Visits to patients in hospitals have been prohibited (except for parents of children under 18 and the immediate family of patients in critical condition or in palliative phase). The guidance of patients during necessary consultations or therapies was limited to a maximum of one person. This measure was only partially binding and enforceable because two out of three Regions had the measure properly formalized. Indirectly, the ban on visiting patients in hospitals could be linked to the Ministerial executive order requiring people to stay home and restricting free movement to only necessary and urgent reasons.

As mentioned above, the hospitals could invoke force majeure. The hospital could classify a visitation ban as a necessary measure to prevent the further spread of the virus. Restrictions can also be imposed by the attending physician. Visitors could not invoke their right to personal freedom of movement to

34 Article 30 Law of 10 May 2015 on the exercise of health care professions, coordinated on 10 May 2015, BS 18 June 2015. The infringement of this provision is punishable (Art. 122, §1, 4°).
35 www.info-coronavirus.be
36 For Brussels: Decision of the Prime minister of the Brussels Capital Region of March 10, 2020 to prohibit, among other things, the visit of persons in nursing homes on the territory of the Brussels Capital Region (article 1 Decision of the Prime minister of March 10, 2020 of the Brussels Capital Region banning meetings of more than 1,000 people, visits to nursing homes and care facilities and school trips abroad, BS March 13, 2020).
37 For Flanders: Decision of the Flemish government of March 13, 2020 to limit access to residential care centers to the residents, staff and volunteers. Visitors will no longer have access to the buildings (article 2 Decision of the Flemish government of March 13, 2020 to take temporary measures to prevent the spread of COVID-19, BS March 19, 2020).
39 The recognition standards for hospitals stipulate that visits of patients can be arranged according to the internal rules of the hospital. The chief medical officer also has
require a visit, since not only their interests are at stake, but also those of others (patients and practitioners). By definition, force majeure can only be invoked in exceptional circumstances and the burden of proof of the force majeure rests with the hospital. An explicit legal provision that defines the scope of application of a visitor ban is recommended.

e) Large-scale testing of the population

Due to the scarcity of test materials and limited testing capacities, Covid-19 tests have only been carried out on two categories of people: 1) those whose clinical condition requires hospitalization and whose attending physician suspects infection; and 2) any healthcare professional complying with the definition of “possible case” and who has a fever. Test capacities are gradually being increased for nursing home and old-age home residents.

Performing a test obviously requires a medical intervention. According to the Patient Rights Act, the patient’s informed consent is necessary. Forced testing is not allowed. Government health care officials may, under the Prevention Decree, subject potentially infected people to a medical examination necessary for the detection of the source of infections. This might be after contact with an infected person who might have transmitted the infection. Government healthcare officials are only able to take these actions in relation to potentially infected individuals - not the general population. Large-scale population testing, if required, falls within the regions’ competences (under the auspices of prevention). There has not (yet) been a legally binding decision taken on mandatory testing, for the presence of the Covid-19 virus, or testing for the presence of immunity from the virus.

responsibility to ensure the proper conduct of the medical department and the hospital board has responsibility for the organization of the hospital (Annex A. III. 4°, § 1 Royal Decree of October 23, 1964 to determine the standards to be complied with by hospitals and their services for the organization and operation of the hospital (Annex A. III. 4°, § 1 Royal Decree of October 23, 1964 to determine the standards to be observed by hospitals and their services, BS November 7, 1964).

40 www.info-coronavirus.be
41 Articles 8 and 14 Law of August 22, 2002 on the rights of the patient, BS September 26, 2002
42 Article 47, §1, 2° Flemish Decree of November 21, 2003 on preventive health policy, BS February 3, 2004.
Mandatory Vaccination

The administration of a vaccine (as soon as it becomes available) also constitutes a medical intervention and requires the patient’s prior consent. Under the Prevention Decree, the Flemish government can draw up a vaccination schedule with “recommended” vaccinations to prevent certain infections. These vaccinations are not mandatory. Government health care officials and doctors may, on the basis of this Decree, require “infected persons” to follow appropriate medical treatment. Such a provision cannot oblige an uninfected person to be vaccinated.

The federal government has competency for “measures on prophylaxis”, which include “mandatory” vaccinations. Mandatory vaccination is made possible under the Health Act of 1945 (as applies to polio) or, for the time it is valid, under the Delegation of Powers Act. Case law, relating to mandatory vaccination schemes against polio, shows that such schemes are not contrary to fundamental freedoms and the Patient Rights Act, because they are a measure to protect public health and public order. The government must adequately justify this measure. A mandatory vaccination scheme is a very drastic and invasive action and should be legitimate and necessary. An earlier Delegation of Powers Act of 2009 (concerning a flu epidemic or pandemic) stipulated that the government could not impose a mandatory vaccination scheme. In the current Delegation of Powers Act, this restriction is omitted.

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45 Article 47, §1, 1° Flemish Decree of November 21, 2003 on preventive health policy, BS February 3, 2004.
47 Article 1(1) 1° Health Act of September 1, 1945, BS October 10, 1945.
48 Royal Decree of October 26, 1966, which makes vaccination against poliomyelitis mandatory, BS December 6, 1966.
49 Act of March 27, 2020 authorizing the King to take measures in the fight against the spread of the coronavirus COVID-19 (II), BS March 30, 2020.
50 Cass. 18 december 2013, T.Geuz. 2013-14, 302, notation S. DALESSANDRO
51 Article 3(2) Act of October 16, 2009 granting permissions to the King in the event of a flu epidemic or pandemic, BS October 21, 2009.
52 Act of March 27, 2020 authorising the King to take measures in the fight against the spread of the coronavirus COVID-19 (II), BS March 30, 2020.
3- Liability and Insurance Issues

a) Acting outside the field of expertise

Physicians are required to provide the same degree of skill and care exercised by the reasonable prudent physician under the same circumstances. The level of care is not simply the “prudent physician”. The law takes into account the specific knowledge of a physician or his/her specialisation. The level of care is influenced by the specialisation of the physician. This is normal, because a physician who has more knowledge and more skills is more competent in that branch of medicine. A physician is judged by the same standard as the physician of the same specialty. A surgeon will be judged by the standard of the ordinary skilled surgeon and an anesthesiologist will be judged by the standard of the ordinary skilled anesthesiologist.

The degree of care is related to the nature of the act. A surgical treatment requires the skill and care of the ordinary skilled surgeon. If the treatment falls outside the physician’s field of expertise, the physician has an obligation to refuse further treatment and to refer the patient to another specialist. If s/he undertakes to treat the patient, the physician will be held to the degree of care of the specialisation which is needed for the specific treatment.

The physician must be aware of his/her expertise and must act within the field of that expertise. A physician takes a risk by acting outside his or her field of expertise, because s/he will be held to a higher standard. If s/he does not meet that higher standard, s/he is negligent.

In the context of Covid-19, Belgian hospitals have decided to shut down some hospital services. This is because of the government’s ban on non-urgent medical interventions and to prevent their intensive care (IC) units from being overloaded if interventions continue in other services. Many unemployed physicians of closed services volunteered to work in IC units.

These volunteer personnel are not really qualified to work in the IC. Is the standard of care that is expected of these physicians lower than otherwise it would be? In principle the answer is no. As mentioned above, the expected standard of care and skill will be based on the post that the physician is fulfilling at the time of an alleged breach.  

The answer would be different if, at the time of the ‘accident’, there were not enough physicians available in the IC and the hospital was forced to call in non-specialised physicians to deal with the increase of patients. The hospital would be confronted with an emergency situation. Desperate times require desperate measures. In an emergency situation, hospitals need every healthcare provider they can get. Working in an IC service, in an emergency situation, does not amount to negligence when the physician lacks the specific expertise, but has the basic skills of a physician or a nurse. The emergency situation would be a justification for handling patients outside the field of expertise, but still treating the patients with basic expertise. The same emergency situation exists when a physician would be requisitioned to work in the IC and to act outside his field of expertise.

b) Telemedicine/triage via telemedicine

A diagnosis requires the physical presence of the patient to make a clinical examination of that patient and/or to order special tests. Prescribing medicine, without having seen or examined the patient, would normally constitute negligence.

In the context of Covid-19, the Minister of Health has issued new healthcare guidelines about healthcare that permit telemedicine. One of the guidelines recommends healthcare providers to limit their consultations to urgent and necessary consultations. Non-urgent and non-necessary medical interventions must be postponed. Consultations remain possible via telemedicine. Several physicians are making diagnoses by way of teleconsultation. This is not always an easy task. A patient who discovers a new pigment spot on his/her body calls the dermatologist who asks the patient to take a picture of the pigment spot and

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57 See also: D. SOKOL, “Can non-specialty doctors on covid wards still be sued?”, www.blogs.bmj.com/bmj/2020/04/16.


to send the picture to him/her by phone. A diagnosis based solely on a picture - without a proper clinical examination - is a risky course of action.

Another specific guideline has been issued about Covid-19 and telemedicine. It recommends that patients with a fever and/or respiratory problems should stay at home, call their general practitioner and report the symptoms. The patient is urged not to go to the waiting room of the general practitioner and not to go to the hospital emergency department. The general practitioner will determine by telephone whether the patient can recover at home or should go to hospital. In principle, the general practitioner has to decide on the basis of an anamnesis by phone.

There are 4 possibilities:

1) If the patient shows only mild symptoms, s/he must stay at home until the symptoms have disappeared. No Covid-19 test is required.

2) If the patient shows severe symptoms, the general practitioner must refer the patient to hospital. The general practitioner has to warn ambulance personnel and the hospital about the arrival of a probable Covid-19 patient with severe symptoms.

3) The general practitioner determines that a clinical examination is necessary to identify the seriousness of the patient’s situation. If the doctor has the necessary protective equipment (mask, special gown, goggles and gloves), they can examine the patient him/herself. S/he can do this during a home visit or in his/her practice by appointment, so no other patients are present in the waiting room. If the doctor does not have the necessary protective equipment, s/he must refer the patient to a triage site or immediately to hospital.

4) If the patient shows up at the doctor’s house, the patient must be isolated and the general practitioner must apply the necessary protective measures.

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These guidelines do not necessarily minimize the possibility of complaints. At the time of writing, the mainstream press has reported two complaints from family members of a patient who died of Covid-19. According to the family, the death of the patient was a consequence of negligence in triage. In the first case, the general practitioner had a telephone conversation with the patient and decided that a hospital transfer was not necessary, because in his/her view the patient only had the flu. The patient then died as a result of Covid-19. In the second case, no general practitioner would agree to make a home visit to a patient with a high 38-degree fever. The patient had to stay in bed and could only take antipyretics for his symptoms. It was only when he could not talk anymore that an ambulance took him to hospital but that was too late to save his life.

One thing is certain: under both guidelines, the physician who makes a diagnosis by teleconsultation carries a heavy responsibility. S/He has to make an assessment of the nature of the symptoms without a clinical examination of the patient. This is not an easy task to undertake over the phone.

In these circumstances, the classic rule applies: an error in the diagnosis is in itself not negligence. Negligence implies that a normal prudent physician would have made another decision. The burden of proof lies with the patient.

A correct diagnosis, at one given moment, can, according to the guidelines, evolve at a later stage. This is why the obligation to inform the patient is of utmost importance. The patient has to be informed about the necessity of contacting the general practitioner again when symptoms worsen or when new symptoms appear or to visit the physician, if possible.

When in doubt about the correctness of a diagnosis by phone, a physician is well advised to make an in-person clinical investigation of the patient or to refer him/her to a triage site or to hospital.

c) Triage in the hospital/nursing home

During the Covid-19 era, triage is not only performed by the general practitioner by teleconsultation but also at hospital for select patients who have access to the IC. Belgium, like any other country, has a limited amount of IC beds. To avoid an abundance of patients and disorganization of the IC unit, most

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64 Newspaper Gazet van Antwerpen, 14th April 2020.
65 Newspaper Het Nieuwsblad, 2nd April 2020.
66 Cf. supra b).
hospitals have issued triage guidelines. On the basis of these criteria, some patients will not be admitted to IC.

This may be contrary to the right of equal access to healthcare. This is guaranteed in the Belgian Constitution\(^67\) but also in international treaties, like the Charter of Fundamental Rights of the European Union.\(^68\)

In times of emergency and limited resources, the right of equal access cannot be guaranteed because there are too few beds for too many patients. By way of analogy, we can refer to the situation of organ transplants, where the demand for organs exceeds their availability. In such situations, the allocation of resources must be decided on objective grounds, without any (illegal) discrimination.

In Belgium, the media has reported that ill, elderly patients from nursing homes should not be transferred to the hospitals but should instead stay at the nursing home.\(^69\) Some Covid-19 documents from medical societies have focused on elderly patients, although they admit that age, in itself, is not a good criterion upon which to ration. It has been observed that elderly residents in retirement homes often suffer from severe cognitive, physical or social disabilities. It is recommended that the general practitioner should proactively discuss advanced care planning with these elderly residents. It is recommended that referral of these patients to a potentially overstretched hospital should only be considered with a clearly defined and realistic therapeutic goal in mind. Referral to the IC unit is not advised.\(^70\)

This headline has caused severe social disturbance. Newspapers and magazines published articles in which it was said that ‘we have lost our ethical compass’, and that it was shocking for anyone to proclaim that the life of senior citizens has less value.\(^71\) Elderly care home residents expressed concern that they were being abandoned and were afraid to become ill, in case they could not access hospital.

\(^{67}\) Art. 23 Belgian Constitution.

\(^{68}\) Art. 35 Charter of fundamental rights of the European Union.

\(^{69}\) Newspaper Het Laatste Nieuws, 24\(^{th}\) March 2020; newspaper Nieuwsblad, 24\(^{th}\) March 2020: “Zwakste rusthuisbewoners met corona gaan niet naar ziekenhuis”.

\(^{70}\) Belgian Society of Intensive Care Medicine, Ethical principles concerning proportionality of critical care during the 2020 COVID-19 pandemic in Belgium, 2020,

\(^{71}\) See e.g. B. BULTHINCK, “Nergens was ons ethisch kompas zo hard het noorden kwijt als in de opvang van onze ouderen”, Knack, 8\(^{th}\) April 2020, www.knack.be/nieuws/auteurs/bert-bulthinck-2475; J. VAN GAEVER, “Drama in de woon-zorg: tijd om de spelregels te herbekijken?”, De Morgen, 21\(^{th}\) April 2020.
From a legal perspective, the wording of these triage documents is unfortunate. Age cannot be a criterion for access to healthcare, because it leads to discrimination. An age-based triage is an illegal discrimination and should be banned. From a policy perspective, it is good that the law protects older people against this kind of discrimination.

Most Belgian hospitals apply objective triage guidelines, based on the well-known and almost universally accepted Clinical Frailty Scale. This scale classifies patients under 9 categories, based on their frailty or increased vulnerability and their reliance on care. In times of scarcity, funds and beds must be used as efficiently as possible, taking into account the likelihood and quality of survival. Of course, age can lead to more frailty. Age is not, in itself, a criterion. A 75-year-old person can be less frail than a 55-year-old person who suffers from obesity and diabetes.

It can be observed that these triage guidelines did not need to be applied. Before the Covid-19 crisis, Belgium had 2037 IC beds. This equates to 18 beds per 100,000 inhabitants. Since the Covid-19 outbreak, the hospitals have created some extra 749 IC beds (converting empty corridors into IC-rooms using Gyproc panels). Due to this and other efforts, Belgium now has 2831 IC beds and 1864 beds were exclusively reserved for Covid-19 patients. On 8 April 2020, Belgium reached a peak of 1285 Covid-19 patients being treated in IC. Since there has never been a shortage of IC beds in Belgium, there has never been a need to apply the new triage guidelines.

There has been a shortage of IC beds in the hospitals of a specific region, namely the province of Limburg. Since hospitals in other provinces still had empty beds, the patients from Limburg were transferred elsewhere. The triage guidelines are simply a last resort or ‘ultimum remedium’. Patients can only be refused a hospital bed when there is no other IC bed available in any hospital, anywhere in Belgium.

A nursing home that refused to transfer a resident to hospital, or a hospital that sent an elderly patient back home, on the sole basis of no available beds (when there are empty hospital beds available elsewhere) or the application of the guidelines, would be acting unethically and illegally.
d) Lack of personnel and/or personal protective equipment

Another possible liability risk concerns a lack of personnel and/or personal protective equipment that leads to a lack of care and/or an increased infection risk. The hospital is, in principle, obliged to ensure the presence of enough qualified staff and adequate supplies of personal protective equipment.72

In the context of Covid-19, complying with these obligations could prove to be difficult.

If a hospital acts in a proactive manner but a shortage occurs, causing damages, it seems unlikely that there will be liability. This is due to the existing national state of emergency and the general knowledge that scarcity is an issue or could prove to be an issue. The hospital could then invoke force majeure.

Proving the causal link between a lack of protective personal equipment and an infection (of a resident/patient or of personnel) with Covid-19 could also be very difficult, due to the widespread nature of the virus. There are similar problems of proof in cases concerning a hospital’s possible liability for hospital generated infections.

e) Defective mouth masks and defective tests

It has been reported that hundreds of thousands of mouth masks, imported from China, have been rejected because they did not meet essential safety requirements.73 If these mouth masks were already in use, they could have given healthcare practitioners a false sense of security. They also could have been a source of contamination.

Hospitals should only work with sound materials. The use of defective materials could lead to liability. In these circumstances, the liability of defective products falls firstly on the producer of these mouth masks, according to the Law on Product liability.74 The organization with the obligation to control the mouth

masks before their use also has an important responsibility. The government who has taken the task of buying and distributing the equipment also bears an important responsibility.

If the hospital faced a liability claim for a defective product, it should bring a counter-claim in warranty against the producer, the control organization and the government. By doing so, the relevant responsibilities would rest where they belong.

It was also reported on 9th April 2020 that the government sent Covid-19 tests to residential care facilities without proper instructions. As a result, sticks designed for use in the throat were instead used in the nose. This caused a lot of pain to residents.

The residents could argue that the personnel should have seen the manual and that their actions were not suited to the sticks’ thickness. This could lead to liability. The residential care facility could also bring a counterclaim in warranty against the government, on the grounds that it should have checked the test kits and manuals before sending them to the residential care facilities. It seems that the final responsibility lies with the government.

f) Liability insurance

The position of insurers is also important to consider in the Covid-19 era. Complaints are unavoidable, so it is of utmost importance that healthcare providers’ liability is covered. Several insurance companies have responded rapidly to the Covid-19 crisis and almost every insurance company has given special attention to the crisis on their website. A list of most common questions and answers (FAQ) is often provided. Several insurance companies have specifically stated extensions of coverage in the context of Covid-19.

The liability of healthcare providers is covered in emergencies, when they act outside their normal competency or outside their field of specialization or if they apply the current triage guidelines.  

76 www.amma.be; www.kbc.be.
g) Temporary immunity from liability?

Following an incident in a hospital in Liège, where an older patient was refused access to the IC department, a proposal was made to grant legal immunity for healthcare providers who act in accordance with scientific guidelines during the Covid-19 period. Healthcare providers who are trying their best should not be exposed to liability claims and years of court procedures.

There have been similar proposals in some other countries. Under the Corona Aid, Relief and Economic Security Act or CARES Act, the US Congress has provided liability protection to volunteer healthcare professionals providing healthcare services. It concerns liability protection but not liability immunity and it is limited to volunteers. Volunteer healthcare professionals will not be liable under federal or state law for any harm caused by an act or omission in the provision of healthcare services during the Covid-19 public health emergency. This protection does not apply when the harm was caused by willful or criminal misconduct, gross negligence, reckless misconduct or a conscious flagrant indifference to the rights or safety of the individual or if the healthcare professional was acting under the influence of alcohol or an intoxicating drug.

Other Belgian scholars have doubted the necessity of such a law. Granting healthcare providers an immunity could be dangerous and sends the wrong signal. It might also be difficult to judge whether or not a medical act is linked to Covid-19. A physician who is forced to work in the IC department is acting in a state of emergency which excludes his/her negligence when s/he is acting in accordance with the relevant guidelines. Liability insurers have confirmed that they will cover possible accidents that occur while working in the IC due to the triage guidelines.

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77 F. DEWALLENS, in the newspaper Het Laatste Nieuws, 6th April 2020.
Some concluding remarks

Belgium has a complex federal state structure. No less than eight ministers are responsible for public health. This complicates the decision-making process. Belgium has been successful in fighting Covid-19 without having to requisition physicians and without causing a breakdown of IC services. There has never been a shortage of IC-beds in Belgium, which shows that Belgian healthcare is well-organized. It seems that the successful focus on the hospitals has been at the expense of the retirement homes where many residents have died. Retirement homes have only recently been provided with protective equipment and tests. The elderly were initially discouraged from going to hospital. The Belgian government should draw lessons from this for the future, in order to respect the principle of equal access to healthcare.
BRAZIL
BRAZILIAN REPORT ON THE CORONAVIRUS CRISIS: A CLASH OF PANDEMICS

Eduardo Dantas¹

Abstract: The outbreak of the COVID-19 hit Brazil, weeks after Asia and Europe, but the country did not adequately prepare to fight the pandemic. As a result of many mistakes, it has now the second largest number of victims on the planet. This article aims to briefly analyze the reasons for the failure in dealing with the sanitary crisis.

Keywords: Covid-19; Pandemic; Social Inequality; Political interference

Although in different forms and severity, the whole world was taken by surprise with the Covid-19 pandemic. What seemed to be just another seasonal disease rapidly spread across the planet, shutting down entire cities, countries, creating an unimaginable scenario, implausible even for the most prolific science-fiction writer.

A new, highly contagious disease, potentially fatal, coming from a virus that no scientist could understand, and with no viable protocols established. No one could predict a world with no flights, no schools, no businesses, with empty cities in lockdown, while the body count skyrocketed everyday in front of the common citizen’s television screens.

This scenario affected the entire world and produced enormous sacrifices from every citizen. Desperate times demanded desperate measures, while mankind rediscovered the notion that public health was the real essential activity to enable survival of the world as we knew.

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It wasn’t any different in Brazil but for an additional complication: the country was hit with a triple crisis. Public Health, Economy and Politics.

The first case was recorded in Brazil on February 25th. As this report is being written, a hundred days later, on June 5th, 2020, the country has now the second largest number of infected people in the world, only behind the United States of America, with official statistics\(^2\), from the Ministry of Health, pointing to 645,438 confirmed cases, and 35,033 deaths (with 3,500 other deaths still pending confirmation).

The official numbers may be underestimated. Among the strategies, adopted to contain the virus spread, testing a large number of the population was not implemented. Studies, conducted by the University of São Paulo (USP), estimated that the number of contaminated people was wrong and could be as much as 15 (fifteen) times bigger than stated in the official statistics, due to under reporting\(^3\).

Large cities, such as São Paulo and Rio de Janeiro, and other important State Capitals, such as Recife, Manaus and Fortaleza, were the main hotspots but there are concerns and strong signs that infections are moving inland into smaller cities with inadequate provisions of intensive care beds and ventilators.

Since the beginning of the pandemic, there was a complete disconnection between the Federal Government and State Administrations. Defending the Swedish solution, of keeping the economy working, with open businesses, and the State Governors defending a more restrictive policy, with social isolation and the opening of only essential services, like pharmacies, supermarkets and food delivery services.

These opposite movements slowed down the measures that needed to be implemented to prevent the spreading of the disease, until the Supreme Court (STF) decided that the State administrations had autonomy to decide their own public health policies, including isolation and lockdown\(^4\). The need to interpret the Constitution could not have arisen at a worst moment, since it was

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biased by the political crisis, established between the President and the State Governors, the Congress and the Constitutional Court.

Strong isolation measures were imposed by the States, among them São Paulo, Rio de Janeiro, Pernambuco, Maranhão, Ceará, and the Federal District. At the time of writing, after almost two months of a not so successful attempts to keep citizens at home, the average isolation rate was around 55%, instead of the necessary rate of 70%. In coastal cities, like Recife and Rio de Janeiro, public parks and beaches were closed to the population, aggravating their anxiety, preventing them from working, and not solving the problem.

These States are preparing to re-open the economy, without accomplishing the original goals of flattening the contagion curve, without a solid plan\(^5\), and preparing to face a possible second wave of the pandemic, with a much more damaged economic structure\(^6\).

The doubling of the rate of deaths is estimated at only 5 days and a recent study by the Imperial College (London, UK)\(^7\), which analyzed the active transmission rate of COVID-19 in 48 countries, showed that Brazil is the country with the highest rate of transmission (R0 of 2·81).

Brazil faces a social and a political crisis at the same time (hence the clash of pandemics highlighted in the title of this brief report). Over 70% of the citizens depend on the public health system which has been vilified by successive administrations, at all levels of government (federal, state and municipal). Brazil ranks among the most unequal countries on the planet. The average monthly income of 1% at the top of the social scale, as of last year, was more than 33 times the average income of 50% at the lowest level\(^8\).

About 13 million Brazilians live in favelas, often with more than three people per room and little access to clean water. Physical distancing and hygiene recommendations are near impossible to follow in these environments—many favelas have organized themselves to implement measures, as best as is possible. Brazil has a large informal employment sector with many sources of income no longer an option.

\(^{7}\) https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-21-brazil/
Most of the State Governors decided to implement social distancing policies, temporarily shutting down all non-essential business activities, with the exception of health services, petrol stations, pharmacies, supermarkets and food markets, deepening an economic crisis, at the same moment that the country started to recover from the destruction caused by the disastrous years of the labor party administrations. Thousands of workers were laid off and many of them already had lost their jobs.

The Federal Government established an emergency program, with a temporary financial aid for workers, that will receive R$ 600.00 (approximately 100 Euros) per month for a three-month period. Other compensations were being established as a Federal aid to the States, who lost a substantial part of their taxation incomes, as a result of closing businesses, in an attempt to lower the infection rates, trying to avoid a collapse in the health system.

The severity of the outbreak, combined with the lack of a coherent political response, has shaken business confidence and caused the national currency to plunge. Since January, the Real has fallen 32% against the American Dollar. Gross Domestic Product is expected to fall 7% or more this year, according to analysts.

In a moment when the country should be united to fight the outbreak, the political divisions have intensified, with the anticipation of a presidential electoral dispute that should occur only in 2022.

Most state governors have come together to criticize the measures suggested by the president of the republic, including taking the dispute to higher courts. The Constitutional Court decided that the main measures, to combat the pandemic, would be defined by the States, and not by the Union.

The national congress adopted measures to pass on the cost of state expenses and debts to the federal government, already weakened by the economic crisis.

Another historic scourge was gaining momentum: with the enactment of a state of emergency, public spending could be made, without controlling bidding, and complaints of overbilling have emerged, turning deaths into a profitable business for corruption.

Personal protective equipment (PPE), medicine, hospital equipment and other biosafety inputs suffered a variation in their prices, if compared with the pre covid-19 prices, suffered a variation of almost 2000% in some cases, making it difficult to offer adequate protection to health workers, especially because
– these materials have basically only one supplier, China, and many countries are competing fiercely for priority purchasing\(^9\).

The political dispute has deepened to the point that it has affected science, at a time when science should guide the decisions taken. The federal government defended the use of hydroxychloroquine as part of the disease treatment protocol, while the state governments reject the idea\(^10\) (perhaps because it was an inexpensive drug and, if it proved to be efficient, it could change the narrative of the need to expand health measures, isolation, removing from governors the possibility of receiving more emergency resources)\(^11\).

The debate generated, with the use of hydroxychloroquine, proved to be too inopportune, since there was no treatment proven to be effective\(^12\). Private hospitals that used the substance have obtained positive results in curing patients, while public hospitals, which were prohibited from using the drug by governors, collected high rates of dead.

In a period of two months, two ministers of health left office, due to differences of opinion with the president of the republic. The country has wasted precious time with irresponsible debates and criminal practices, stirring up disputes at a time when there should be unity against a common enemy.

The results are clear with the advance of the disease, in a scenario of lack of control and lack of health planning, and it is foreseeable that the fight, against the pandemic, will last much longer and cause thousands of deaths, before being successful.

Non-essential industrial and economic activities remain paralyzed, deepening the crisis, and the main strategy of state governments is distance and social isolation.

In most cities, wearing masks has become mandatory and outdoor activities remain prohibited.


\(^10\) [https://saude.estadao.com.br/noticias/geral,entenda-a-liberacao-de-cloroquina-e-hidroxicloroquina-no-brasil,70003265490](https://saude.estadao.com.br/noticias/geral,entenda-a-liberacao-de-cloroquina-e-hidroxicloroquina-no-brasil,70003265490)


Hospitals continue to suffer from the historic deficiency of materials and supplies and health professionals have been contaminated at a much higher rate than those seen in other countries.

Brazil has the largest rate of contaminated health professionals. According to the Ministry of Health, there has been 31,790 health professionals that were contaminated by Covid-19. Another 114,000 cases remain under investigation. Among physicians, there has been more than a 100 reported deaths and, according to the Federal Council of Nursery, there has been 143 deaths among nurses\textsuperscript{13}, the highest rate in the world.

As a result, these are some of the issues faced at this moment:

The Country has now the second largest number of deaths in the world, second only to the United States. There has been propositions for the unification of treatment (and sharing of Intensive Care Unit (ICU) beds), from the public and private sectors, but there is no legislation regulating this and such measures could open the door to legal problems that would disorganize the private sector for decades. Brazil has the size of a continent, and very different realities in every region and in all of its 26 States and the Federal District, with different (and most of the times conflicting) political interests in all of them, which makes the task of defining a single combat plan near impossible.

During the last days of May, the Senate passed a law\textsuperscript{14} (pending approval of the parliament) regulating the possibility of the Administration to seize ICU Beds and other private hospital units if necessary, to accommodate patients from the public sector. Half of the ICU beds in the country are administered by the private sector, while the other half, which are public, should cover three quarters of the population. During a health crisis, this simply doesn’t work. There is little or non-existing regulation on how to take over this private equipment, how to pay them and clear rules on liability\textsuperscript{15}.

The public sector suffers from the lack of adequate equipment (respirators, medicine, and hospital units) to combat Covid-19 and lack of Personal

\textsuperscript{13} https://oglobo.globo.com/sociedade/coronavirus/brasil-ultrapassa-marca-de-cem-medicos-mortos-por-covid-19-dois-por-dia-1-24438369
\textsuperscript{14} https://agenciabrasil.ebc.com.br/politica/noticia/2020-05/senado-aprova-requisicao-obrigatoria-de-leitos-privados-pelo-sus
\textsuperscript{15} http://www.cremepe.org.br/2020/05/05/justica-faz-confiscos-de-leitos-e-rede-privada-teme-desorganizacao-com-fila-unica-para-coronavirus/
Protective Equipment (PPE) for nurses and physicians is a daily challenge (reflected in the aforementioned death toll) since governments were not even remotely prepared to face the pandemic.

Brazil has become a classic example of incompetence in crisis management, making the task of saving lives even more difficult, demonstrating that there is no plan to rebuild the country’s economy after the social and health devastation.

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CHINA
Editorial Prerogative and Explanation

Introduction
At the time of going to press, with this special issue of the Journal, Medicine and Law, every paper contained, within this issue, was subjected to independent academic referral and review from experts in the field. Authors were invited to respond to the referee(s)’ comments and their contribution further reviewed. Once accepted for publication, every paper, within this issue, was edited by two independent English speakers to adjust for language, grammar and syntax and returned to the relevant author(s) for final approval of content and format, to ensure that none of the import had been inappropriately modified, consequent to the process. With the exception of the following paper, this process was adhered to with absolute rigor, resulting in some author(s) declining to proceed because of the need for considerable additional effort required to accommodate the expectations of the referee(s). The paper to follow went someway down this path, but not all the way, and it is for that reason, and for the fact that its inclusion is as a direct consequence of editorial decision to meet the needs of this particular special issue, that it was felt that an additional explanation was mandated.

As set out in the editorial which has accompanied this special issue of the Journal the evolution of this issue was as a consequence of the cancellation of the August, World Congress on Medical Law, planned for Toronto, Canada. Each national representative, on the World Association for Medical Law (WAML) Board of Governors, was invited to provide a focused national perspective of that country’s experience of the Covid Pandemic in its first half year. Most of the Governors responded positively with few exceptions.

Late within this process, the WAML was advised of the resignation of the Chinese representative, Prof Chunfang Gao, from the Board of Governors. This would result in an obviously highly relevant gap and a deficiency in what was to be an authoritative ‘time capsule’ to cover the first half year of the Covid Pandemic. Based on the widely held premise, still to be verified by stringent academic investigation, the pandemic originated in China and any ‘time capsule’, reviewing the pandemic, without a Chinese commentary, would be considered either biased, deficient or at least incomplete. Upon the advice of the resignation of the Chinese governor from the WAML, the editor in chief approached a number of highly regarded, internationally recognised Chinese academics who, with the exception of Prof Yushen Sha, politely declined the offer of inclusion.
Prof Sha, the Secretary General and Vice President of the Chinese Health Law Society, was most accommodating and was prepared to make a contribution to the Journal, to fill the void and to present the Chinese perspective of the Pandemic. It is with great gratitude and respect that I acknowledge his willingness to contribute to this special issue. Both time and other considerations have restricted the process, relevant to Prof Sha’s contribution, and the only way forward, within these constraints, was for the Executive Editorial Committee to exercise a decision to include the paper as correspondence while recognising these limitations. This has translated into there being less oversight and some problems with editing, other than to evaluate syntax and grammar, but without this paper, offering the Chinese perspective, the whole concept of this ‘time capsule’ would have lacked a degree of relevance.
CHINA’S PRACTICE OF FIGHTING NOVEL CORONAVIRUS PNEUMONIA

Yushen Sha*

Abstract: China adheres to reliance on people and regards public knowledge as an important prerequisite for building a sound communication and interaction between government and the public and forming a strong consensus. Based on the sense of social responsibility, and the sense of trust in the government, the public actively participates in the fight against the epidemic, forming a situation of “one mind and one mind”. Flexible and humanized social control and non-medical intervention, based on traditional isolation, have become the key factors to curb the spread of the epidemic; the investigation, detection and monitoring, based on epidemiological investigation, have become the key links to cut off the transmission chain of the virus and the implement of timely treatment for patients; hospitals are set up in different levels and patients are divided into light, medium and severe patients, according to the condition classification, and the integration of traditional Chinese and Western Medicine are adhered to, aiming to greatly reduced the infection rate, disease death rate and improved the cure rate. One should give full play to the advantages of the system, allocating resources efficiently throughout the country, launching logistics support war, and wining the “Hubei defense war” and “Wuhan defense war”, with national strength. China has achieved important results in epidemic prevention and control at different stages. Based on the actual situation of China, one should sum up and improve the practice, and try to explore a set of effective “Chinese practice” and “Chinese methods” in controlling the epidemic situation and treating patients.

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Keywords: Practice; Novel Coronavirus Pneumonia Pandemic; Fighting; Integration of Traditional Chinese and Western Medicine; Epidemic Prevention and Control

Introduction

Regarding the novel coronavirus pneumonia pandemic, the fastest spreading, widespread infection and the most difficult public health emergency in the past hundred years, China has persisted in taking the people as the center and adopted the most comprehensive, strictest and thorough preventive and control measures. It has resolutely blocked the whole country’s epidemic situation with great courage and strength. The spread of the disease has achieved important results in the prevention and control of the epidemic. How to effectively deal with the global pandemic, which is a once in a century situation, remains a world problem, to be solved by the international community. Based on the actual situation of China, China followed the objective law of infectious disease prevention and control, summarized and improved while practicing, and constantly met new challenges, striving to explore a set of effective “China practice” and “China practice in controlling epidemic situations and treating patients Method “.

1. Social Consensus and National Mobilization

   A. Timely, comprehensive and transparent release of epidemic information;
   B. Popularize scientific knowledge of prevention and control;
   C. The mainstream media strengthens the guidance of public opinion and provides public opinion support; and
   D. The participation of the whole population to form social synergy

2. Social Segregation and Traffic Control

China is a large-scale floating population society. In the absence of vaccines and specific drugs, non-medical interventions, based on traditional isolation, are the most basic and effective means to block the spread of major epidemics. In the face of the outbreak of the new crown epidemic, China has implemented unprecedented large-scale public health response measures, “upstream blocking” to cut off the source of infection in severe areas; other areas have “comprehensive prevention and control”. Unconventional social isolation
measures and flexible and humanized social control have blocked the spread of the virus in a large area and become the most critical factor to curb the spread of the epidemic in the country.

A. “Closure” and “decommissioning” are implemented in “severely affected areas”;
B. Implement hierarchical traffic control in non epidemic areas;
C. Avoid personnel aggregation and cross infection by various means; and
D. Take community isolation as the basic defense line to block the virus.

3. Troubleshooting and Dynamic Monitoring

Based on the understanding of the infectious law of “human to human transmission” of virus, the investigation, detection and monitoring, with epidemiological investigation as the core, is a key link to cut off the transmission chain of virus and the implement of timely treatment for patients. China attaches great importance to: “prevention and control at source”; implements the prevention and control policies of “early detection, early reporting, early isolation, early treatment”; and “due inspection, due collection, due separation and due treatment”; and takes “early detection, early reporting” and “due inspection, due separation and due treatment” as the priority, which plays an important role in reducing the infection rate and mortality rate.

A. Community based comprehensive investigation;
B. Improve the detection level;
C. Establish a dynamic management system;
D. Carry out flow regulation in depth; and
E. Identify four types of personnel for classification.

4. Diagnosis and Treatment Plan and Treatment Capacity

The sudden and concentrated outbreak of the epidemic led to a serious run on medical resources and patients could not be treated in time which, not only led to the spread of the virus, but also directly led to a high death rate, which was the biggest challenge in the early stage of the fight against the epidemic. In accordance with the requirement of “putting medical treatment first”, put forward by Chinese leaders, China has always “put treatment as the top priority” at the beginning of the fight against the epidemic, adhered to
the principle of “life first”, especially made clear the policy of “full collection of receivables”, “early diagnosis and treatment” and “centralized treatment”, especially the policy of “integration of Chinese and Western medicine”, and set up hospitals in different levels and classified them according to the disease level. One should treat light, medium and severe patients with free treatment at the same time to relieve the patients’ worries, avoid serious illness and death caused by disease and expand the source of infection, greatly reduce the infection rate, disease death rate and improve the cure rate.

A. Establish the dual objectives of controlling the source of infection and improving the treatment;
B. Improve the treatment plan and optimize the treatment means; and
C. Chinese medicine participates in the whole process with the advantages of “treating the disease before treatment”, “syndrome differentiation and treatment” and “multi-target intervention”.

5. Resource Allocation and Material Support

China should give full play to the institutional advantages of “concentrating on major issues” and establish a national system to fight against the epidemic. It should carry forward the national spirit of “one party has difficulties and eight parties support”, support the severely affected areas with national strength, take the national support for Hubei and Wuhan to fight the epidemic as the key to win the “Hubei defense war” and “Wuhan defense war”, and coordinate and allocate the resources of the whole army as the “main battle”. One should allocate resources efficiently throughout the country, optimize production organization, strengthen emergency supply of medical materials and necessities, strictly investigate and deal with all kinds of illegal acts of ‘price gouging’, making and selling ‘fake’ goods, win logistics support war and lay an important material foundation for fighting against the epidemic.

A. National medical personnel rushed to Hubei;
B. Strengthen the production and supply of medical materials and medical support services; and
C. Coordinate the support of living materials as a whole.
6. Command System and Strategic Policy

After the outbreak of novel coronavirus pneumonia, the general campaign was also called “blocking war” and “overall war”. The effective “quasi wartime” leadership and command system and the strategy formulated, according to the time and situation, provide strong leadership, fundamental compliance and scientific guidance for China’s fight against the epidemic.

A. Top leadership decision-making mechanism and basic strategic policy; and

B. Efficient implementation mechanism and comprehensive response measures.

Conclusion

Unity is strength. One should carry forward the international humanitarian spirit, undertake the shared historic mission, jointly build a community of common health for mankind and timely benefit the front-line medical personnel and the general public, at home and abroad, with technologies and products, so as to build a strong defense line towards universal security and lasting prosperity worldwide. As long as all countries make concerted efforts, one will be able to withstand the challenge and accomplish the ultimate triumph against the pandemic.

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FRANCE
THE FIGHT AGAINST THE COVID 19 EPIDEMIC IN FRANCE: HEALTH ORGANISATION AND LEGISLATIVE ADAPTATION

Anne-Marie Duguet* and Emmanuelle Rial-Sebbag**

Abstract: The sudden and unpredictable nature of the Covid 19 epidemic exposed all countries to organize the fight according to their health system, culture and resources. The responses have been different and, as the pandemic developed, countries have been affected by the virus in different ways. Expertise gained in previous outbreaks, such as Severe Acute Respiratory Syndrome (SARS), was not transferable in Europe because of the different means and social contexts. Knowledge of the virus and the modes of contamination have gradually improved, starting at the end of January 2020. The start of this pandemic only considered those with symptoms to potentially transmit the virus. Knowledge of transmission of the virus by healthy carriers necessitated widespread preventive measures, such as barrier actions and population containment.

Public health policy in France has gradually prepared for the arrival of the virus with the activation of prevention plans, since the initial announcements of World Health Organisation (WHO). The epidemic has developed in France from clusters and the healthcare system has adapted to accommodate more and more patients. A health emergency law has been enacted. The impact of the law, on human rights, health regulations in the distribution of products and services, biomedical research and social protection and issues of ethics raised by these emergency measures are presented in this article.

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France was among the most affected countries in Europe by COVID-19, after Great Britain, Spain and Italy. Between March 1 and May 22, 144,556 cases were detected and 100,038 patients hospitalized with 28,289 deaths. The French health system has responded to the epidemic at the cost of considerable efforts to prepare and adapt hospital services (to double the capacity of reception in resuscitation services) and mobilize health professionals practising at home and in health care facilities. A health emergency law was enacted and population containment was effective from March 15 to May 11. In addition to the provisions of Social Security Insurance, to fully support the care of all patients, measures to help businesses have been offered by the government, to limit the social consequences of the shutdown of the economy.

1- PUBLIC HEALTH POLICY AND HEALTH CRISSES

The state guarantees, without discrimination to all persons, equal access to care required by his/her state of health. France is a centralized state that gives the same access to care and prevention throughout its territory. The Social Security Insurance system is open to anyone staying in the territory, to fund sickness and maternity care, even to illegal immigrants (with certain reservations).

In order to protect public health, the State historically had general administrative police measures, the application of which is the responsibility of the Prefects and to a certain extent, the Mayors through the Departmental Health Regulations. The Public Health Code organises the prevention of health risks in its Title III.

In 2004, the Public Health Policy Act 2004-806 was established, including: a High Council of Public Health\(^1\), a national body of expertise in public health; and a National Public Health Committee responsible for ensuring inter-ministerial and inter-institutional coordination in the field of health security and prevention. The National Health Risk prevention plan (Art L.1311-6 CSP), developed over 5 years, takes into account biological, chemical, physical and meteorological risks.

In the event of a serious health threat (Article L.3010-1), the Minister of Health may, by reasoned order, prescribe any measures proportionate to the risks. The

\(^1\) www.hcsp.fr English presentation available
merits of the measures are subject to periodic review by the High Committee of Public Health according to terms defined by decree in the Council of State (Art L.3110-2 CSP).

The state representative in the region (Director of the Regional Health Agency) defines how to implement national objectives in a Regional Public Health Plan (Article L. 1411-11 CSP). Each health facility has a crisis system: the white settlement plan that allows it to immediately mobilize the resources at its disposal, in the event of a massive influx of patients, or to deal with an exceptional health threat (L.3110-7 CSP). This plan is an anticipatory plan that enables the organization to be implemented in order to respond to the epidemic at its advent.

Other control measures are planned, such as disinfection of premises and sanitary transport vehicles (Article L 3114-1 CSP) and border health control, in accordance with the World Health Organisation (WHO) International Health Regulation to prevent the spread of communicable diseases by land, sea or air. (Art L 3115-1 CSP).

**Anticipating Health Crises: Contingency Plans**

There have been contingency plans that can be activated in institutions (white plans) since 2004 and a national plan, the ORSAN plan, since 2014.

The White Hospital Plan is a crisis mechanism, activated by the Director of the hospital, with the aim of immediately mobilizing the means, of any kind at its disposal, in case of an influx of patients or to deal with an exceptional situation, in agreement with the Regional Health Agency.

It details the management of alerts and relationships with the authorities and the media, coordination with the SAMU (Emergency Medical Assistance Service) to ensure the care and transport/transfer of patients to appropriate care facilities, the recall and allocation of available medical personnel and distribution of human resources, the use of all beds and care facilities and certain closed units and the mobilization of temporary economic and logistical resources made available, as well as the communication with police services.
The ORSAN Plan: Organizing the Health System’s Response to Exceptional Health Situations

Created in 2014, this plan organizes, for the whole territory, the response of the health system in exceptional health situations: ambulatory, hospital and social. It was partially applied in 2014 for the arrival of the Ebola virus in France, in 2015 for seasonal influenza (18300 deaths), and for the terrorist attacks in Paris in November 2015 and Nice in July 2016.

The goal is to optimize emergency patient care while continuing to welcome patients not directly involved in the event. It was activated by the Minister of Health for COVID 19 on 23 February 2020.

In dedicated or expert institutions, the plan provides for a front-line device that must receive patients 24 hours a day, with regulation (assessment and guidance) organized by the SAMU. The second line supports regulated patients with a match of means. Level 1 of the plan is internal mobilization to accommodate for large numbers of patients. Level 2 is the white plan of hospitals that increases human resources, with the recall of personnel and the release of beds (by cancelling programmed interventions). The management of patient flows is organized according to the criteria of prioritization/orientation linked to severity: absolute emergency or relative emergency. The actions are coordinated by the hospital’s crisis committee.

2- ALERTS AND FIRST STEPS TO FIGHT AGAINST COVID 19

a) WHO and the Covid 19

One of the WHO’s historic responsibilities is to administer a global regime to fight the international spread of diseases. The WHO adopted an International Health Regulation (IHR) in 1951 to prevent the spread of disease from one country to another, applicable in all countries. This regulation outlines border controls (ports, airports, border crossings) because the development of international travel and trade facilitates facilitates the rapid spread of epidemics. The IHR has been reviewed regularly and since the eradication of smallpox, there are only 3 forty-year-old diseases for which border controls are carried out: yellow fever, plague and cholera.

When the Severe Acute Respiratory Syndrome (SARS) outbreak appeared in 2003, as the first global public health emergency of the 21st century, the WHO formed an intergovernmental working group to propose a new IHR that aimed to prevent, protect, control and respond to the international spread of disease,
through a proportionate public health action, limited to the risks it poses to public health, avoiding unnecessary barriers to international commerce. States are bound by convention to develop minimum critical public health capacities and to notify the WHO of what could constitute a public health emergency of international concern; the WHO makes temporary recommendations after taking into account the advice of an emergency committee.

First WHO announcements:

On 31 December 1979, the Wuhan Municipal Health Commission reported cases of pneumonia with a new coronavirus, the WHO set up a central, regional and national support team on 1 January and issued its first outbreak bulletin on 5 January 2020. On January 30, the OMS qualified the outbreak as a “public health emergency of international concern”. On March 12, the pandemic was declared.

**b) The Covid Epidemic in France**

Preparing for the arrival of the virus

After China released the virus sequence on 10 January, 16 French institutions were designated as reference centres. Following China’s decision to confine Hubei Province, on 22 January, Paris-Wuhan air links were cancelled. From 31 January, France evacuated its nationals from Wuhan and several successive flights were organized with medical teams on board. Upon arrival in France, passengers were placed in solitary confinement under medical supervision in isolated and protected sites.

The Ministry of Health’s Operational Centre for Regulation and Response to Health Emergencies (CORRUSS) was set up to on January 27 to anticipate the arrival of the virus. The ORSAN plan and its ORSAN REB component were launched on 23 February.

**The Start of Infection in February: Clusters**

On 8 February, 5 cases were detected among foreign tourists in Contamines-Montjoie. The first death, in France, was recorded on 14 February, a Chinese national. On February 25, the first Frenchman died. On 27 February, 20 new positive cases were recorded around the Creil airbase, which houses the Wuhan repatriation military airbus. On 5 March, several clusters were identified: Oise, Val d’Oise, Upper Rhine, Lower Rhine, Mulhouse, Morbihan and Ajaccio. On 6 March, 85 cases were detected in Mulhouse, after a religious gathering.
Specific measures were being taken in the affected areas: no more meetings, schools closed.

**The Spread of the Epidemic: Political and Regulatory Measures under the Authority of the Prime Minister**

To free up beds in hospitals, non-urgent interventions are deprogrammed from 6 March. The Covid Council of Scientists was set up on 10 March. On 11 March, visits to the EHPAD (homes for elderly) were prohibited. The closure of nurseries, college schools, high schools and universities was ordered on March 12. The municipal elections took place on 15 March with protective measures, in the evening, the closure of all non-essential public places was effective except for pharmacies, banks, food stores, gasoline/petrol stations, tobacco offices and press offices. On March 16, after advice from the Council of Scientists the containment was organized and only activities strictly necessary for the life of the nation were allowed. The borders of the Schenghen area were closed, but French people, staying abroad, were be able to return. On 22 March the adoption of the State of Emergency Act and the Principle of Ordinances occurred.

**3- STATE OF HEALTH EMERGENCY**

The special state of emergency regime allowed exceptional powers to be used in exceptional circumstances, in the event of disasters or epidemics, the law of which defines the modalities of initiation and processing. Two successive laws were enacted.

**Health Emergency Act 2020-290²**

The first law defined the state of health emergency in its Title 1, then the economic emergency and adaptation measures to fight the epidemic (Title 2) and finally the electoral provisions (Title 3).

The health emergency was pronounced for 2 months, until 23 May 2020.

The Committee of scientists was created³, its president was appointed by the President of the Republic, a member by the President of the National Assembly

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³ Art L. 3131-19 of the CSP
and one by the President of the Senate, the other members were appointed by decree. The committee periodically provided advice on the state of the health disaster, the scientific knowledge associated with it and the measures to eradicate it. Notices were made public without delay.

The main provisions made by decree of the Prime Minister for the sole purpose of guaranteeing public health were:

restrictive measures of freedom to come and go:

1-restricting or prohibiting the movement of persons: prohibition of people from leaving their homes subject to travel strictly essential to family or health needs;
2-quarantine of people at risk of becoming infected under the 2005 International Health Regulations;
3-to put in place isolation measures at home or in a suitable accommodation; and
- additional measures
5-order the temporary closure of public-friendly establishments, such as: sports stadiums, cinemas and theatres, department stores;
6-make appropriate medicines available;
7-order the requisition of goods and services, and any person necessary for their execution; and
8-order temporary price controls on certain products.

This law attracted wide commentary from human rights experts and lawyers, on: the proportionality of the measures in terms of their purpose; on the consequences of the exceptional regime; and on attacks on the freedom to come and go.

4 Article 3131-15 CSP and Decree 2020-293 of 23 March 2020
These restrictive measures may be appealed to the administrative judge: procedures for suspension or removal of liberty (Art L.3131-18 CSP). Many actions have been brought which largely have been dismissed\(^7\). The government has also been blamed for its handling of the crisis. It is possible to file a complaint against the members of the government before the Court of Justice of the Republic (CJR) to engage their personal liability in the performance of their duties. As of May 13, 63 complaints had been filed\(^8\). In response to these complaints, the CJR’s 18-member request committee decided whether or not to proceed and possibly refer the matter to the Investigating Commission.

**Law 2020-546 Extending the State of Health Emergency\(^9\)**

The state of health emergency was extended until 10 July 2020. The new law maintained certain provisions, including criminal conditions, such as the periods of pre-trial detention and the conditions of release; after advice from the Committee of scientists, the conditions of quarantine were specified for air or rail passengers; and the place of isolation, at home or in a dedicated place (hotel). Special derogatory provisions were provided in cases of domestic violence, to prevent the perpetrator from remaining close to potential victim(s).

The placement in isolation for 14 days was conditional on the medical finding of the infection and possibly extended in the same way. It could be controlled by the judge of freedoms or be the subject to a complaint by the Prosecutor of the Republic.


\(^8\) https://www.lemonde.fr/societe/article/2020/05/14/covid-19-deja-plus-de-soixante-plaintes-contre-des-membres-du-gouvernement_6039643_3224.html

A new chapter has been added for provisions of the creation of an information system to fight COVID 19, which aimed to adapt existing information systems and provide for data sharing. The personal data collected is to be kept for 3 months, such as virological or serum status of the subject, evidence of clinical diagnosis or medical imaging, transmitted by a doctor or a medical biologist. Health surveys were planned to identify contact subjects and to support these individuals. Contracted health workers could be assigned to this collection and compensation arrangements were provided. All people with knowledge of this information were subject to professional secrecy and could be prosecuted in the event of a breach. In accordance with French law, every person has the right to access and correct the information collected. When using this data in epidemiological studies, the names of individuals and their national identification numbers is deleted.

A monitoring and liaison committee to involve civil society and Parliament in operations to fight the spread of the virus included at least 4 parliament members. The committee assessed the feedback, the actual contribution of digital tools and whether or not they made a significant difference in the treatment of the epidemic. Throughout the transaction, the Committee verified the guarantees of protection of personal data and respect for professional confidentiality. A detailed report on the implementation of the measures was sent by the government every 3 months to Parliament (public notice).

4 - IMPACT OF THE STATE OF HEALTH EMERGENCY ON HUMAN RIGHTS

The emergency laws, passed by the states to fight infection with Covid 19, restricted a number of rights and freedoms enshrined by the ECHR\textsuperscript{10}. In the majority of European states, a large part of the activities has been interrupted.

If the indivisibility of human rights was not called into question, Article 15 allowed for a derogation from respect for certain rights, subject to conditions, “in the event of war or other public danger threatening the life of the nation”.

The fight against COVID 19 was not a state of war but a danger, threatening the health of the nation. The aim was to balance the interests in favour of a

\textsuperscript{10} Carole Nivard « Le respect de la Convention européenne des droits de l’homme en temps de crise sanitaire mondiale » La revue des droits de l’homme Actualités Droits-Libertés 2020 Avril https://journals.openedition.org/revdeh/8989
social rights, the rights to health protection (Article 11 of the European Social Charter) and the civil and political rights and freedoms enshrined by the ECHR.

The rights affected were freedom of movement, freedom of assembly, the right to respect for property, the right to respect for private and family life, freedom of expression and the right to free elections.

Violations of these rights were justified in the name of protecting health and maintaining public order, as long as they were proportionate to the public interest pursued. The measures, taken in the States, were compatible with these requirements. EcHR jurisprudence recognizes the potential to restrict certain rights offered by the ordinary regime, recognizing a principle of proportionality by referring to the preservation of health, or public health for health security.

Absolute rights that do not contain a public order clause are indesigent: the right to life, the prohibition of torture and inhuman and degrading treatment, the legality of crimes and punishments and the prohibition of the death penalty.

France did not request the waiver clause for Covid 19, even though this had previously been the case in the state of emergency declared for the fight against terrorism.

5- REGULATORY IMPLICATIONS OF THE HEALTH EMERGENCY LAW

Off Label Prescriptions: Exceptional Authorization for Drug Use in the Covid Pandemic 19 Decree 2020-314

The issuance of products out of their marketing authorization was provided in an exceptional way, for rare or serious diseases where there is no appropriate treatment (Art L 5121-12 CSP). As a derogatory way, the Decree allowed the dispensing and administration of the two products under the responsibility of a doctor in health facilities. ANSM is developing a protocol for the use and modalities of patient-friendly information.

Therapeutic surveillance was accompanied by the collection of information of adverse events with transmission to the regional pharmacovigilance centre. In its opinion, the High Committee recommended that therapeutic trials be implemented in parallel. In the absence of validated treatment, various drugs were used to treat Covid 19 because they have been shown to be effective in other epidemics. The decree 2020-314, issued as part of the state of health emergency, taking into account the opinions of the High Committee of Public
Health of 5 and 24 March, described provisions relating to the availability of medicines outside their marketing authorization (AMM): hydroxychloroquine and lopinavir/ritonavir.

**Reshaping Research and Clinical Trials**

For research, our institutions have favored the engagement of research centres into accelerated processes to fund and support related COVID-19 research activities. As a consequence, some of deadlines for regular submission of research programs were postponed by the National Agency for Research (ANR) and new calls related to COVID-19 were launched with a faster selection process and implementation. The scope of the programs was broad, from basic science to social and humanities projects. Clinical trials started engaging several clinicians and leading to several scientific controversies.

In the evaluation and authorization of research protocols on COVID 19, the French National Agency for Drugs, ANSM for scientific evaluation and the research ethics committee and Committee for Protecting Persons, for the respect of the law regarding research, made efforts to design fast track evaluation procedures. Time for the assessment was reduced to one to two weeks for the two institutions, instead of 2 months in regular periods. According to ANSM’s last point of information (April 10, 2020), 52 COVID-19 clinical trials were submitted in France with 35 of the protocols authorized and some others awaiting complementary information. France was contributing to 7 European clinical trials. Among them Inserm (The French National Institute for research and health) is leading the DISCOVERY European trial (recruitment in France and Luxembourg) aiming at conducting a phase III clinical trial comparing various therapeutic strategies.

**Teleconsultations and COVID**

Teleconsultation was a mode of exercise recently developed in France. It was allowed by the Social Security insurance in 2018, with a refund of the same level as that of the traditional consultation. Its aim was to facilitate citizens’ access to care, throughout the country, especially in areas of low medical density. It also promoted coordinated management between health professionals (tele-expertise). Teleconsultation was organized on a secure messaging platform, with the patient’s consent, and carried out with a patient already known to the doctor, part of the coordinated care pathway. To consult a specialist, the referring physician had to designate the specialist to the patient. Some specialists were in
direct access: ophthalmologists, gynaecologists, stomatologists, pediatricians, psychiatrists and neuropsychiatrists. The occurrence of COVID 19 has encouraged the development of teleconsultations by all health professionals and the Ministry of Health has proposed, on 18 March, an information guide for professionals wishing to practice telehealth (telemedicine and tele-care) and the High Health Authority has drafted recommendations.

Decree 2020-227 allowed for a derogating from the coordinated care pathway and the doctor’s prior knowledge of the patient. In addition, the 2020-428 ordinance introduced the 100% refund until the end of the state of health emergency. Teleconsultation was open to midwives.

Decree 2020-459 authorized teleconsultation as an act performed by telephone when video transmission was not possible.

Between 23 and 29 March, 486,369 teleconsultations were billed and 44% of GPs teleconsulted.

**6- IMPACTS ON SOCIAL PROTECTION**

For patients: The Social Security insurance fully supports the care and hospitalization of patients with COVID 19 and reimburses the tests carried out on medical prescription. In addition, the Health Emergency Act extended all measures to maintain access to care, until July 10, for benefits that would end during the state of emergency, such as renewals of drugs prescriptions or of nursing care or medical benefits.

Decrees regulated the way in which health professionals accessed masks, the prices of hydro-alcoholic gels, drugs used in treatment and certain relevant hospital products.

Work stoppages could be prescribed (covered by the medical insurance) for parents who were forced to stay at home to care for their children.

There were exemptions to adapt the conditions for opening or extending the rights or benefits of people with disabilities, people living in poverty, beneficiaries of social minimums and the elderly.

For professionals: the incomes of liberal health professionals have dropped significantly because attendance at their practice also has declined significantly during confinement due to patients’ fear of contracting the virus, despite being allowed out to their doctor’s office.
The CARMF, independent doctors’ pension fund, which also managed pension plans for incapacity to work, took important steps to help professionals. A first aid was provided by the deferral of charges for 3 months (compulsory contributions for their retirement) and the management of the disability of doctors sick of COVID or in fragile situations during the epidemic (5000 files). On 15 May, the fund granted an additional 2000 euros to each practitioner. This was a total of 8,000 euros per doctor if indirect aid is taken into account.

7 - ETHICAL ASPECTS OF THE COVID CRISIS

The National Ethics Advisory Committee issued opinions at the request of the government, parliamentarians or academic structures. These opinions were advisory and had no binding force for those who requested them, but were very high quality references.

An initial opinion was delivered in 2009 on “ethical issues raised by a possible influenza pandemic.”

In 2020, the CCNE believed that the general ethical principles, identified in opinion 106, remained relevant. The whole society had to engage in a process of responsibility and solidarity towards vulnerable populations: the elderly, people with disabilities, homeless people, those deprived of their liberty, children in institutions, migrants... at risk of unequal access to care and attacks on dignity. Then the CCNE made 4 recommendations: 1) to set up a joint body of scientific experts of disciplines in conjunction with members of civil society; 2) to establish an ethical support committee to deal with the management of scarce resources (resuscitation beds, mechanical ventilation) to assist health professionals as closely as possible to defining their care priorities; 3) to encourage innovation, pooling services, use of computer tools; and 4) to organize a quick feedback and independent evaluation.

On March 30, the CCNE argued for protection measures to have been strengthened in elderly homes and long care facilities, even in the absence of suspected or confirmed cases. Containment, which was accompanied by a ban on family visits to EHPADs, added the emotional risk of isolation to

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11 www.carmf.fr
12 www.ccne.fr accessible in English
13 Opinion 106
14 Réponse du 30 mars sur le renforcement des mesures de protection dans les EHPAD et les unités de soins de longue durée.
the epidemic risk. The CCNE considered that exceptional binding measures were mismatched with the usual basic requirements of care support and that respected human dignity including maintaining a social bond. Any binding measure had to be adapted, proportionate and adequate to individual situations, explained to residents, families and subject to control. All means (human and resources) had to be identified and mobilized: organization of separate areas and preservation of a traffic space. A secure welcome could be envisaged for residents at the end of their lives. Any strengthening of containment measures had to be decided by the medical coordinator of the facility. Ethical support cells could be set up.

8- THE EUROPEAN COLLABORATION

The COVID 19 epidemic showed that there was no coordination between states at the EU level, as Article 42-7 of the Treaty of the European Union would have allowed.15

The EU provided support to cross-border healthcare delivery in its Communication issued on April 3, 202016, recalling its legislation regarding cross-border health care17. The Commission encouraged the EU Member States to rely on the existing mechanisms to facilitate the delivery of care at the time of the crisis.

Even though the COVID-19 epidemic lead mainly to national ruling and decisions, it was critical that France engaged to a certain level of collaboration with European partners and European institutions.

In order to help the medical services that were overloaded by COVID-19 cases admitted in intensive care units, in the East of France, several patients were evacuated, at the end of March, beginning of April, to several medical centers in Germany, Luxembourg and Switzerland. As for the two first countries, the transfers were operated under the umbrella of the European Air Transport Command (EATC). This French-German initiative coordinates the activities of 7 Member States (The Netherlands, Belgium, France, Germany. Luxembourg, Spain and Italy) in the field of military air transport, air-to-air refueling and aeromedical evacuation.

CONCLUDING REMARKS

The French State has had to deal with an unpredictable situation due to its magnitude and seriousness and its exceptional provisions were implemented. Public opinion was particularly critical of the Government: only 34% of French people believed that the government lived up to the situation. A survey\(^{18}\) of 1,000 French, 500 British, 500 Italians 500 Spaniards and 500 Germans found that 63% of British, 60% of Germans and 50% of Italians were satisfied, as were 32% of Spaniards.

A clear lack of confidence affected the French, who consider that the government had not told the truth and had not made the right decisions at the right time: 43 to 45% of Europeans agreed with these proposals, compared to 23 to 25% among the French. There was also a mistrust about vaccination, as 25% of French people will not be vaccinated should a vaccine against Covid 19 be found\(^{19}\).

The public wants a drug that is available quickly so that they can resume their previous lifestyles. It did not accept uncertainty when scientists said that this virus was new and that one must wait for the results of the studies. Distrust of political decisions was linked to an irrational concern caused by containment and fostered by the constant dissemination of unvalidated information through the social networks.

\(^{18}\) https://www.lepoint.fr/tiny/1-2374910

HUNGARY
HEALTH AND LEGAL POLICY IN HUNGARY AT THE TIME OF COVID-19 PANDEMIC

Judit Sándor¹

Abstract: Just as in many countries, the Covid-19 pandemic has posed unprecedented challenges to the Hungarian society in a variety of ways. It was a test to the health care system which had already lacked resources even before the pandemic: deteriorating infrastructure, worsening hygienic conditions, and growing scarcity of doctors and nurses had impaired the health care sector. While it seems that the country survived with a relatively little loss in the first wave of the epidemic between February and May, some political and social changes will remain with us even after the pandemic passes. It has become obvious that the techniques of containing the epidemic can be extended to implement stricter political control over the population. Deploying military rhetoric have also contributed to the normalization of the state of exception: people, in general, got used to the “state of danger” and accepted the disciplinary measures as normal. This fight to suppress the epidemic have therefore strengthened populism in the country as it proved to be a continuation of fights against other enemies (migrants, minorities, foreigners, etc.) in order to unite society behind its leaders. Based on these mixed elements of health and political control, it is necessary to discuss public health measures and extending political control in parallel with each other, as they are inseparable in our biopolitical reality today.

Keywords: Covid-19; Hungarian Health Care; State of Danger; Enabling Act; Pandemics

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Beginnings: Hesitation and Delay

When at the end of December 2019, Chinese public health authorities reported several cases of acute respiratory syndrome in Wuhan, the capital of Hubei province, we did not pay too much attention. Since then we have learnt that the disease, known as the coronavirus disease 2019 (Covid-19)\(^2\), represents a completely new strain of coronavirus that has not been previously identified in humans. This novelty created a lot of uncertainty about the way the virus could spread, about the symptoms, and about the necessary measures to stop the pandemic. In January 2020, following the news about the Covid-19 epidemic that rapidly developed in Wuhan, it was like watching a terrible dystopian movie. It did not seem to be close. Even when scientists and doctors revealed that this virus could spread from human to human, people still did not realize the upcoming and real threat.

This pandemic taught many things; among them that politics play a crucial role in fighting against coronavirus but also in shaping what one knows about it. In many countries affected by the pandemic, politics has become the medium through which scientific knowledge is channeled to the public: sometimes distorting it, sometimes emphasizing biased information.

In the middle of February, Europe was not yet prepared for a pandemic, and the outbreak was still regarded as an isolated epidemic in a region of China. At the end of February, for example, Hungary, together with Austria and the Czech Republic, sent masks and necessary equipment to Wuhan.\(^3\) Then everything changed suddenly when alarming news came from Italy, a country frequently visited by Hungarians and just 300 km away from the Hungarian border.

In Hungary, the first political response to the pandemic was the establishment of the so-called Operational Group Responsible for the Containment of the Coronavirus Epidemic on January 31, 2020. The Chief Medical Officer, Cecília Müller, and the representatives of the Operational Group have held daily press conferences since then, reporting on Covid-19-related events and the measures taken by the government.\(^4\)

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\(^2\) The causative virus is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)


\(^4\) 1012/2020. (I. 31.) Korm. határozat a Koronavírus-járvány Elleni Védekezésért Felelős Operatív Törzs felállításáról
Second Phase: The “State of Danger” Declared

The first measures implemented by the government involved a fourteen-day quarantine for those who returned to Hungary from Italy and China, and later from Iran. In the beginning the quarantine was based on voluntary compliance. Then on March 4 the first case of coronavirus infection was reported: it was an Iranian pharmacology student at Semmelweis Medical University, who had returned from Iran on February 22. Shortly after this the government cancelled its official ceremony for March 15, an important national holiday. Government Decree No. 46/2020 (March 16) introduced restrictions on the opening hours of stores, pubs, restaurants, theatres, and cinemas, it cancelled public gatherings, cultural and sports events; and made non-compliance with the restrictions a petty offence.

Government Decree No. 40/2020 (March 11) declared the “state of danger” in the entire territory of Hungary in order to “eliminate the consequences” of the pandemic. The “state of danger” in case of a natural or industrial disaster is to be distinguished from the constitutional category of the “state of emergency”, which refers to a military conflict. The decree refers to Article 53 of the Fundamental Law of Hungary, which prescribes that “in the event of a natural or industrial disaster endangering lives or property, or in order to mitigate the consequences thereof, the Government shall declare a state of danger, and may introduce extraordinary measures laid down in a cardinal Act of Parliament.” The article does not mention a pandemic among the natural disasters, specifically, but more importantly, it does state that the type of extraordinary measures introduced by the government has to be laid down by a cardinal law, that is, an act passed by a two-thirds majority.

This decree on the state of danger had an automatic sunset after 15 days without parliamentary authorization. On 23 March, the government submitted the Act on Protecting against the Coronavirus to parliament to ask for the decree to remain in legal effect.

The parliamentary opposition wanted to ensure that there was a time-limit to the period of danger and they also rejected the expedited procedure, so the decree expired on 26 March. In the interim period, between 26 March and

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5 On May 11 when gene sequencing of the virus was disclosed then it was revealed that the virus in Hungary had appeared much earlier and originated from numerous different mainly European sources.

6 “State of danger” is the literal translation of the Hungarian term “veszélyhelyzet”.
30 March, the government and the head of the National Public Health Centre issued new orders on restricting people’s movement. The so-called *Corona Virus Act* was renamed by the Hungarian public the *Enabling Act* because it gave the government a parliamentary mandate to rule by decree without a set time limitation (a sunset clause).

**Third Phase: The Adoption of the Act on the Containment of the Coronavirus**

The governing parliamentary supermajority passed the Act No. XII of 2020 on the Containment of the Coronavirus on March 30. Commentators started to use the informal title Authorization Act (even Enabling Act,7) as from the perspective of constitutional law this Act effectively authorized the Prime Minister, Viktor Orbán, to rule by decree for an unlimited period of time. The Enabling Act cancelled the elections and referenda until the crisis was over.

The Act No. XII of 2020 on the Containment of the Coronavirus8, states that the National Assembly may take all necessary emergency measures to prevent and remedy the human epidemic of Covid-19 in 2020, in particular the possibility that the National Assembly may be adjourned due to the human epidemic.

The government quickly closed down ordinary courts due to this pandemic. The only state institution, formally independent from the government, that could continue its operation was the Constitutional Court, but it cannot serve as a check on the government. Cases can come to the Constitutional Court, through the ordinary courts, but since the courts are in recess this avenue has been blocked.

Certain officials (such as the prosecutor general, the ombudsman, and also the government) may still ask for constitutional review but the state officials were all chosen by this government, from among those friendly to their party. The Constitutional Court has been packed with political allies, so no one can expect an impartial constitutional review.

Section 3 of the Enabling Act states that the Parliament may withdraw its authorization before the end of the period of state of danger.

By this it created an unprecedented power for the government, which used its

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7 The term “Enabling Act” refers to the Ermächtigungsgesetz of 1933. Since the pressure and protest by the European Union against this law without sunset, the law was promised to be withdrawn and the state of danger will be replaced by the “state of health danger”.

8 2020. évi XII. törvény a koronavírus elleni védekezésről
power to contain people, irrelevant to the state of infectious spread in Hungary. This was likely a clear indication that the government used this power for other measures, not only for the emergent circumstances.

The Enabling Act was also discussed in Brussels, at the European Parliament. Although the debate, held on May 14, did not result in binding measures, many European politicians stated that the Act violated basic European principles of the rule of law and the separation of powers. As a consequence, the Prime Minister’s Chief of Staff, Gergely Gulyas, stated that the government could end emergency powers in late June, depending on the evolution of the pandemic.

Increasing political powers during the state of danger is not specific to Hungary. One could find similar motivations and maneuvers in different parts of the world, including Thailand, Russia, or Azerbaijan. In Poland, for example, the governing party Law and Justice uses the pandemic to introduce further restrictions on abortion, while it is not self-evident at all how this might help to stop the pandemic.

**Freedom of Speech and Expression during the Covid-19 Epidemic**

Heidi J. Larson is right by saying that “when governments or their leaders repress pandemic information in the hope of calming anxious publics, or deliberately release supposedly reassuring misinformation, they risk undermining their own credibility and their abilities to help people to counter real health threats.” To defeat the coronavirus, one needs access to reliable information and facts, including a free press.

The Hungarian Coronavirus Act punishes the dissemination and spreading of false information about the virus, with up to five years in prison. Freedom of expression and access to information are crucial factors as transparency of information enhances the compliance with the harsh measures of the epidemic. Another feature was the appointment of new, semi-military functions for the head of the hospitals who are controlling the current situation, to increase transparency issued in article guidelines mandated during the pandemic.

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10 Hospital commander, in Hungarian: “kórházparancsnokok”
The Enabling Act further weakened the freedom of speech and press by criminalizing the obstruction of epidemiological control and the publication of false or distorted facts that interfered with the “successful protection” of the public. Both these newly formulated crimes are broad enough to be used against critics who challenge governmental measures.

**Basic Statistical Figures**

At the time of writing this paper, the number of people diagnosed with contracting the coronavirus in Hungary was 3,921, of whom 532 people have died (314 from the capital) and 2160 left the hospital after recovery, and 189 969 tests have been conducted.\(^\text{11}\)

In comparison with last year’s mortality statistics, there has been no excess death rate. The Hungarian Covid-19 related figures do not seem to be high in comparison with the death tolls in Italy\(^\text{12}\), Spain, the United Kingdom or the United States. Hungary took measures relatively early and schools were closed in two steps, first universities and then elementary schools and high schools. Social distance measures were also implemented and the borders were closed.

The most problematic element in dealing with the coronavirus crisis was the lack of transparency. Many feel inadequately informed about the reasons behind different measures. Pandemic information should not be limited to reporting on the daily number of infections, deaths, and the measures introduced, but should also include explanations that even lay people can understand, as well as the sources and methodologies of collecting information.

The Operational Group decided that when they were reporting on Covid-19 deaths the underlying diseases would be mentioned as well. As the number of cases was low at the beginning, the 16–20 people who died could be identified easily. The list indicated that alcoholism was the underlying disease for a middle-aged man, and many internet users could make the immediate connection with a person whose sudden death was mourned by his colleagues in the diplomatic service. In another case, the Operational Group could not resist the temptation to mention that a 37-year old woman was obese. Human dignity is a right that should be extended beyond the individual’s death, and underlying conditions should not be made public beyond the immediate circle of family members,

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\(^{11}\) [https://koronavirus.gov.hu/last update: 2\textsuperscript{nd} of June 2020]

\(^{12}\) In comparison, in Italy where the current death toll is 33,475 [https://www.worldometers.info/coronavirus/country/italy/ last accessed on 2\textsuperscript{nd} of June, 2020]
especially in case of non-public figures. From an epidemiological perspective it would appear as if the underlying conditions were more relevant than the Covid-19 related disease and the coronavirus itself.

**Suspension of Non-Emergency Treatments and Evacuation of Hospital Beds**

Although there was no specific decree about this matter, several health care services were suddenly suspended in the middle of March, leaving many patients without adequate health care. They may become the invisible victims of the Covid-19 pandemic.

The treatment of patients who are not infected with coronavirus has become complicated. During the pandemic this group of patients seems to be forgotten, even though their illnesses and health problems have not disappeared. Indeed, one could surmise that the constant stress, confinement, lack of physical activity, and the deferment of screening will lead to a worsening of existing conditions. Those whose conditions pose an immediate threat to their lives cannot do without treatment. As the epidemic continues, those whose conditions were not originally life-threatening, may now worsen significantly. It matters whether an operation, intervention or checkup is put off for a duration enough for an illness to deteriorate. This deferment of treatment will impact the overall death rate and the number of patients lost in intensive care. The capacity of the healthcare system constantly must be increased, because with the eventual disappearance of the epidemic, treatments that were deferred will need to be given, and the condition of some of those who were waiting will have become acute.

On Good Friday, a holiday in Hungary, the Minister of Human Capacities, Miklós Kásler, ordered up to 60 percent of the hospital beds in Hungary, to be emptied and prepared for the coronavirus patients. Many patients, with a postoperative conditions or in the terminal phase of cancer, were sent home. This unprecedented action which shocked families was not based on any particular law. Directors of the health care institutions who did not comply with this measure were summarily dismissed.

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Rehabilitation, patients and employees of the Institutional, organized a demonstration which nevertheless had no effect on the dismissal.

**Ethical Guidelines**

Over the last few decades, bioethics has focused on new technologies, such as genetic intervention, biobanks, gene-editing, and artificial reproduction. Europe’s most comprehensive and legally binding set of bioethical norms, the 1997 Oviedo Convention, prescribes that, “The interests and welfare of the human being shall prevail over the sole interest of society or science.”\(^\text{15}\) The document’s drafters at the time were more concerned with cloning and genetic treatment than a disease outbreak.

Perhaps more applicable today is the convention’s Article 3: “Parties … shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.” This principle, while important, does not address the difficult question of what to do when medical resources are suddenly in short supply, as they presently are.\(^\text{16}\)

The Hungarian Medical Chamber adopted an important document on the ethical aspects of the Covid-19 pandemic.\(^\text{17}\) The Ethical Guidelines set up rules on how to triage patients in case of scarce resources. The principles presented in the document are based on a utilitarian approach, maximizing the benefits in the allocation of scarce medical resources by giving priority to those people who have a higher chance of survival. The criteria applied in prioritization are strictly medical and therefore age cannot be considered as a criterion itself. The guidelines’ use of a multifactorial criteria, to avoid discrimination against the elderly, arises when the dilemma of life and resources becomes drastic choice made by others than that of the patient. Since mid-March hospitals planned and delivered medical services only for life-threatening conditions and emergency conditions. Such disparities of care raised issues of quality and harm that may occur due to the sudden rise of COVID-19.

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The intent of the guidelines were benevolent and useful, but they failed to recognize that during this pandemic where far more uninfected patients suffered from the lack of adequate medical treatment than were those who were infected.

**Age Specific and Geographical Restrictions**

Among the death cases high number of people (over 100) were the patients who lived in elderly homes. There were tragic cases of death, especially in the elderly care homes in Budapest and in Fejér county.\(^{18}\) Since it was unclear who should have tested these patients, after returning from hospitals, the large number of positive cases later provoked significant tension between the government and the Mayor of Budapest. Retrospectively, it is obvious that the policy should have focused on the protection of the elderly and health care workers by providing protection, tests from the beginning of the pandemics.

The elderly have been given exclusive right to enter shops and pharmacies between 9 a.m. and 12 noon. People younger than 65 may enter the shops only early morning or in the afternoon and shops are open only until 3 p.m. (except for grocery stores and pharmacies). This measure meant to protect the elderly and was upheld even in early June.

Since May 4, different rules apply for Budapest and its surrounding Pest County, on one hand, and the rest of the country, on the other. While the restrictions were prolonged for the capital city, free movement was granted in the countryside. Moreover, while residents of Budapest were not allowed to travel to the countryside, not even to their weekend houses, people living in the countryside could visit Budapest, come and go, any time.

**Fourth Phase: Reopening Medical Services and Representative Survey**

On May 4, the Operational Group declared the gradual opening of some medical services. There were still uncertainties about the conditions to access health services. Some interventions and examinations, such as dentistry, require a Covid-19 test, even though it is still not generally available, and it remains unclear as to its financing in the private sector. The quality and availability of tests are still uncertain.

On May 1, 2020, under the leadership of Semmelweis University, the four Hungarian medical schools launched a nationwide, representative coronavirus screening, to gain an accurate picture of the extent and dynamics of the epidemic.

As a part of this so-called, H-UNCOVER survey, 17,778 people across the country were invited to take part in a screening survey. They were selected by the Central Statistical Office, to ensure that the sample was representative of the 7 regions, as well as age and gender. The first results showed an extremely low infection rate among Hungarian citizens, indicating that drastic measures, such as evacuation of 60% of hospital beds, were overcalculated and unnecessary.

**Other Legislative Changes During the Pandemic**

Vulnerable groups often suffer further harm during states of exception or emergency, in this case the state of danger. Madison Powers makes a distinction between socially situated vulnerability and natural vulnerability. During the pandemic, the focus is often on people who have a medical vulnerability (it is more likely that they become infected or develop more serious symptoms), so various forms of social vulnerability are often overlooked. This may result in serious violations of individuals’ rights during emergencies: minorities, refugees, and women often face greater difficulties in accessing healthcare and decreased social protection with increased rates of violence.

Although domestic violence is a serious issue in Hungary and is still increasing, during this lockdown, two days after the National Mothers’ Day, the Hungarian Parliament adopted a political declaration, initiated by the Christian Democrats, on rejecting the Istanbul Convention. The co-ruling party said parliament should refuse to ratify the convention, citing the content and its definitions of gender. The political declaration stated that the Council of Europe document takes an unacceptable approach to defining gender and parliament should not incorporate this approach into national law. The political declaration also called on the government not to go any further in acceding to the convention and to lobby the European Union to do likewise.

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19 [http://www.ksh.hu/huncover](http://www.ksh.hu/huncover) last accessed on 12 May 2020


21 [https://www.coe.int/fr/web/conventions/full-list/-/conventions/rms/090000168008482e](https://www.coe.int/fr/web/conventions/full-list/-/conventions/rms/090000168008482e) Council of Europe Treaty Series - No. 210 last accessed May 4, 2020
Many women’s organizations struggled for years for the ratification of the Convention. The increasing misogyny and the silencing of female politicians during this pandemic are dangerous phenomena, and it only makes matters worse that domestic violence is on the rise since people were forced to stay at home to work in the home office.

Conclusions

Societies face a risk that the conduct of science has become indistinguishable from politics. There were many different policies implemented in the world, from the Swedish model of prompting herd immunity to the strict lockdown system of Wuhan. Both extreme solutions: leaving social interactions open and the implementation of strict sheltering, curfew and social isolation have been observed around the globe. The Hungarian policy was a moderate lockdown policy with gradual opening in May.

It is a general observation that Central Europe had significantly less reported cases of Covid-19 than did Western Europe. Mandatory vaccination practice, relatively early reaction to the epidemic and strong governmental control on disseminating information about the figures of the pandemic, are some reasons for this regional discrepancy.

In early June it is still difficult to fully assess the successes or failures of different Covid-19-policies. We still do not know when health care services will be accessible for everyone and when this uncertain situation will end. There are three important messages that have already been crystallized: first, it is necessary to increase the capacity of health care services to make them

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Council of Europe Convention on preventing and combating violence against women and domestic violence, Istanbul, 11.V.2011

22 Hungary, Poland, and Slovakia have the lowest amount of cases of coronavirus in Europe with approximately 50 confirmed cases per million people, according to the National Agency for Communication and Information Technologies (NAKIT). The Czech Republic also ranks near the bottom in Europe in terms of coronavirus cases, coming in 16th in the European Union and seventh in the number of performed tests. The country features 265 cases per million people. Source: https://rmx.news/article/article/hungary-poland-and-slovakia-have-lowest-amount-of-coronavirus-cases-in-eu-per-million-people

23 In Europe there are 161 420 covid related deaths; the five countries reporting most deaths are United Kingdom (34 466), Italy (31 763), France (27 625), Spain (27 563) and Belgium (9 005). [Data on 17th of May by the European Centre for Disease Prevention and Control] accessed on 17th of May, 2020 https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases
better prepared for similar epidemics and pandemics in the future; second, the individual’s right to health care should be more clearly articulated; and third, all segments of society should have better access to scientific and medical information. If governments monopolize the information flow, then it can easily distort or delay adequate action that is essential to minimize the consequences of a pandemic. Scientists should also feel free to warn the public and explain their findings, to empower the public to require and receive transparent information.
HONG KONG
PUBLIC HEALTH ACTIONS AGAINST COVID-19 TO PROTECT OUR RIGHTS TO HEALTH

Albert Lee*

Abstract: The rights to health cover a very wide perspective, not limited to conventional health services, during the pandemic of COVID-19. Public health measures should go beyond implementation of public health regulations and should build up community capacity and good local governance to put effective health interventions into practice, within the local context. Governing bodies need to serve the common good, balancing the benefits of public interest and limitation of individual freedom in compliance with the principle of proportionality and requirement of “absence of arbitrariness”. Public health law should also protect the rights entitled by the citizens from exposure to risks. Proactive public health actions and the role of primary health care should be emphasised in the health system and the socio-economic determinants of health for infection control. The public actions against COVID-19 have illustrated the need to ensure the rights of the population to healthcare services that meet timely needs.

Keywords: COVID-19; Rights to Health; Public Health Actions; Pandemic; Health Protection; Law and Regulation; Human Rights; Governance; Community Care; Health System

Background: What Constitute Rights to Health?

International Covenant on Economic, Social and Cultural Rights (ICESCR), article 12, provides that “The States Parties to the present Covenant

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recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.\textsuperscript{1} The Committee on Economic, Social and Cultural Rights (CESCR), General Comment 14, explains that “right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health.”\textsuperscript{2} CESCR describes the determinants of health including (not limited to):

- Adequate supply of safe food and nutrition
- Housing
- Access to safe and portable water and adequate sanitation
- Safe and healthy working conditions
- Healthy occupational and environmental conditions
- Access to health-related education and information

Frieden’s Health Impact Pyramid has identified the socio-economic factors with a higher impact on public health with reduced costs and efforts from individuals,\textsuperscript{3} compared to clinical intervention of individuals. There is a call for governments to strengthen or create a legal framework to ensure rights-based Universal Health Coverage (UHC) on the basis of principles of equity and non-discrimination, including affordability, financial protection, transparency, accountability, participation, privacy and sustainable financing (UN, 2019).\textsuperscript{4}

Essential elements consist:

1. Availability - public health and basic healthcare facilities, goods, services and programmes

2. Accessibility - non-discriminative, without barrier, right to seek and receive health information


3. Affordability - economic accessibility
4. Acceptability - sensitive to culture, gender and life-cycle requirements
5. Assurance of quality - skilled healthcare personnel, quality healthcare facilities, evidence-based healthcare practice and safety

With regard to the recent COVID-19 pandemic, what should constitute the rights of health for our citizens? Gostin’s work, in global health justice, elucidates the key determinants of global health equity and how they can help citizens around the globe against COVID-19.

**What are the Essential Public Health Services for COVID-19?**

**Effective Public Health Interventions for Infection Control**

The epidemiological triangle of the three main factors - agent, environment and host in the pathogenesis of communicable disease explain why there is a need to implement rigorous preventive measures to contain the infectious agent and establish environments inhibiting the spread of infection to prevent outbreak of communicable diseases. Measures, such as face mask wearing, hand hygiene, physical distancing, restriction of social gathering and ‘shut down’ measures are effective precautionary measures against influenza and respiratory infections. Prem et al. have highlighted that the implementation of physical measures has a strong potential to reduce the peak magnitude of COVID-19 and lead to a decreased number of cases. Cautions must be taken when lifting these physical measures prematurely, as it could lead to a

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second wave of outbreak\textsuperscript{10}. A Study, in Hong Kong, has also found that non-pharmaceutical interventions (including border restrictions, quarantine and isolation, distancing and changes in population behaviour) were associated with reduced transmission of COVID-19, similar to the substantially reduced rates of influenza transmission in early February, 2020\textsuperscript{11}. Conflicting views will arise with the implementation of restrictive public health measures, along with uncertainty on the impact on commerce. In low income countries, these measures would have a direct impact on daily living: this may include: shortage of food supplies and essential products; lack of access to essential services; and unemployment. How should essential commerce and public safety be balanced?

The definition of public health as ‘\textit{collective and collaborative actions for sustained population-wide health improvement}’, by Beaglehole et al\textsuperscript{12}, underscores general public interest with a focus on the broader determinants of health and indicates cooperation for a supportive system to improve public health. Adoption of protective and precautionary behaviours requires people to have an appropriate level of risk perception with the belief that effective protective actions are available (response efficacy) and confidence in their abilities to engage in protective actions (self-efficacy).\textsuperscript{13} Miscommunication or misunderstandings of public health information would lead to: inaccurate understanding of risk; increased high-risk settings; and may further dissolve the public’s appropriate behaviours and measures. This may be exceptionally adverse to specific highly susceptible groups in the community.

\textsuperscript{10} Ibid
Public Health Services at Municipal Level

Public health measures, targeting populational health crises, need to develop appropriate responses in municipalities by strengthening community action. Public health authorities should work closely with local community leaders and local key stakeholders to:

- Design and deliver effective health communication to local community achieving appropriate level of risk perception meeting the local circumstances and needs.
- Ensure key messages are approachable for the local community.
- Break barriers for uptake of precautious measures and avoid culture of blame, stigmatisation and discrimination.
- Mobilise local resources to help community families with at-risk members.
- Maintain solidarity, supportive spirit and cohesiveness for effective local governance, to ensure smooth coordination of measures for the pandemic.

Many basic and low-cost interventions, such as wearing facemasks and hand hygiene could reduce the transmission of respiratory viruses. These interventions are particularly important when definite treatment and vaccination are not available. Hand sanitisation facilities might not be readily available and there might not be adequate supply of face masks, as reflected in this current crisis of COVID-19 infection. Public health measures may be augmented to address the social environment of the municipality to wholly support communal features that improve health and living conditions.

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15 Ibid
health services should emphasise a communal sense of health for structured and integrative health promotion and constitute a platform to generate or alter local policies.\textsuperscript{18} The concept of Healthy City, involving a high degree of public participation to reduce societal factors that may affect one’s life and health, should be the goal of health governing bodies to enable the local municipality’s integration and development of appropriate policies in preparation for crises.\textsuperscript{19}

Public health should avoid being driven by a narrow focus on biomedical research or reforms on clinical services: community health empowerment must not be neglected\textsuperscript{20}. Extremes of state driven and market driven health systems must be addressed to shift their focus on an informed and healthy public. Collective and collaborative actions, aiming for sustainable health improvement of the population, would help untangle these conflicts. Public health action will need to facilitate good governance, particularly at the local level, while addressing human rights, social-economic factors and universal health coverage.

**Governance for Pandemic Preparedness and Response**

**Importance of Good Governance**

It is unlikely that the World Health Organisation (WHO) International Health Regulation (IHR)\textsuperscript{21} would translate the measures mentioned to be in place in different countries. Many measures will require local actions to take place, within the setting where people live, work, study and play. Legal measures are not a panacea for implementation of preventive public health measures. There is a discrepancy between society’s need for law and conflict against law. Legal concepts would be the basis for different organisations to enforce regulatory mechanisms as well as engagement of different stakeholders to uphold these rules and regulations.

\textsuperscript{18} Tord Kjellstrom (Chair and Lead Writer) et al. Our cities, our health, our future: Acting on social determinants for health equity in urban settings. Report of the Knowledge Network on Urban Settings, WHO Commission on Social Determinants of Health. WHO Centre for Health Development, Kobe, Japan – 2007. \url{http://www.who.int/social_determinants/resources/knus_report_16Jul07.pdf}


Pandemic preparedness and response is more than infection control and requires good local governance. It is not just about the action of the government but the sum of individuals and institutions, public and private, to plan and manage the common affairs of local municipalities. At the municipal level, the local authority has a better understanding of the local population and their needs and can lobby for support with consultation and joint planning. Actions at municipal level can include:

- Communicating directly with local community leaders, local key stakeholders, local citizens to understand the rationale of international and national guidelines, with high degree of transparency, allowing them to express grievances and difficulties and solicit their support as well as supporting them to achieve best possible solutions benefitting the whole community.

- Planning jointly with local community leaders, local key stakeholders and community representatives to overcome the barriers for implementation of various physical measures in an orderly fashion, meeting the local needs and priorities.

- Ensuring adequate local supply of basic protective measures, such as face masks, hand sanitisers, temperature checking devices by mobilising resources available.

- Deploying adequate manpower resources for effective implementation of guidelines, such as physical distancing, restriction of social gathering and population movement, wearing facemask in public places and reinforcing hand hygiene.

- Working closely with local community leaders and local key stakeholders to create social norms to comply with various preventive measures.

- Identifying facilities, within the locality, for isolation, quarantine and conversion to “community hospitals” for borderline cases, in consultation with local community stakeholders and representatives.

**Governance at Municipal Level for Pandemic Response**

Municipal infrastructure must consider the role of Non-Government Organisations (NGOs) vs Government organisations, private and public partnership and networking with cross sector collaboration, to strengthen
community action. All these require strong local governance with supporting municipal policies and administration. Successful adaptation to stressful events and challenges of living, such as living in pandemic condition, requires the local community to incorporate the resiliency capacity. Community resiliency is a process of linking network of adaptive capacities after a public disturbance\textsuperscript{23}. The core elements, building community resiliency, are local knowledge; community networks and relationships; communication; health; governance; leadership; resources; economic investment; preparedness; and mental outlook\textsuperscript{24}. Good governance can enable government institutions to mobilise and coordinate resources at various levels of society\textsuperscript{25}. Even appropriate solutions may fail when imposed in a top-down manner, without engagement and implementation by the stakeholders. National governing bodies can provide adapted policies and local governance should innovate to meet the local needs, especially if the illness had become more severe or the period of societal disruption prolonged\textsuperscript{26}.

Good local governance can empower the community to appropriate level of risk perception, translation of national guidelines into local context and strengthen community health promotion to better prepare and respond to pandemics. Municipalities can effectively implement action plans for rapid response, mitigation and recovery phase\textsuperscript{27}.

**Human Rights in Response to Pandemic**

**Benefits and Rights of Measures against Spread of Infection**

Public health measures for situations like pandemic influenzas can infringe upon the rights of individuals for the benefit of the public.\textsuperscript{28} A member of the


\textsuperscript{27} Supranote 14 [Lee]

community must have access to the resources that emphasise health from a boarder perspective, such as the information provided in Table 1\textsuperscript{29}.

**Table 1. Measures against Spread of Infection: Rights and Benefits** \textsuperscript{28-29}

<table>
<thead>
<tr>
<th>Measures</th>
<th>Possible infringement of private rights</th>
<th>Benefits</th>
<th>Rights entitled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Border control and travel restriction</td>
<td>Restriction of freedom of movement and trade</td>
<td>Prevent cross border spread of infection</td>
<td>Protecting the community exposure to ‘imported’ potential hazards</td>
</tr>
<tr>
<td>Isolation and quarantine</td>
<td>Detention and depriving freedom of movement</td>
<td>Separating the potential cases from healthy population</td>
<td>Health protection of population at large, preventing exposure to potential hazards</td>
</tr>
<tr>
<td>Restricted social gathering</td>
<td>Impeding the spread of infection in public places</td>
<td>Freedom of association</td>
<td>Public safety minimising exposure to risk of infection</td>
</tr>
<tr>
<td>Strict hygiene measures, e.g., face wearing in public place, use of hand sanitiser</td>
<td>Controlling individual behaviours, inconvenience</td>
<td>Reduce transmission among close contacts</td>
<td>Enhancement of health literacy and capacity of effective self-protective measures</td>
</tr>
<tr>
<td>Hospital infection control to restrict visiting</td>
<td>Impact on family lives, rights of patients to be visited by relatives</td>
<td>Reduce transmission among patients, healthcare workers, families and community</td>
<td>Protection and prevention from nosocomial infection</td>
</tr>
</tbody>
</table>

Systematic review has shown poor hand washing techniques\textsuperscript{30}. If handwashing facilities cannot be in place, appropriate use of hand sanitisers, especially before and after entering public places, would be an option. Should the use of hand sanitiser, before and after public places, be mandatory? Wearing face masks has been shown to be protective against airborne and droplet


\textsuperscript{30} Supranote 16 [Jefferson et al]
infections. Should public places enforce face mask wearing? Do operators of public utilities have a duty of care to protect people patronising the services? If customers become infected, due to lax preventive measures, would the operators be liable for negligence and can damage be claimed? Would people being warned of risk and not taking the required precautions be liable for potential victims? If physical distancing is shown to be effective, will this impose a duty of care for responsible parties to implement? Would those who refused to comply be liable?

Public Health Law in Safeguarding Population Health and Human Rights

Section 47 of Ireland’s Health Act 1947 requires a “person” to take precautions against the infection of other people with particular infectious diseases and failure to do so, as well as transmission of infection, may lead to action against him/her. The court shall presume that the infection was a direct result of the failure to take precautions, unless the defendant can prove that it was unlikely to be caused by failure to take precaution. The definition of “person” shall be body corporate, unincorporated as well as an individual, as defined in section 18 of Interpretation Act 2005, Ireland. This would open claims against individuals and organisations failing to take appropriate steps to prevent the spread of infection, in breach of requirements under Health Act 1947,

In public health emergencies, would local municipalities make use of resources for isolation and quarantine? Local municipalities should also be empowered to reorganise arrangements for local transport, public service provisions, logistic for supplies and deliveries. In UK, powers are available to ministers, health and local authorities to minimise the spread of the COVID-19 and its health ramifications.31 The local authorities, under the Health Protection (Local Authority Powers) Regulation 201032 and the Health Protection (Local Authority Power) (Wales) Regulation 201033, are able to request and require action to be taken to prevent, protect against or control a significant risk to human health. The Health Protection (Coronavirus) Regulation 2020 in England34 confers power to the Secretary of State or a public health consultant to impose proportionate and necessary restrictions and requirements on people to reduce the risk of spread (Regulation 5 and 8).

32 SI 2010/657
33 WSI 2010/1544
34 SI 2020/129
Human rights are about how one treats others, not how we treat ourselves. Global health policies should be promoting common and public values serving the interests of all. In *Enhorn v Sweden*, the applicant was a homosexual man, infected with HIV virus, and had transmitted the virus to another man. The county’s medical officer issued instructions to the applicant, under the Infectious Disease Act 1988 (Sweden), mandating him to comply with requirements, such as use of condoms, informing sexual partners, consulting doctors on a regular basis and limiting alcohol. The applicant failed to comply with the instructions and the county’s medical officer succeeded to seek court order to detain him in isolation for 3 months. The applicant complained to the European Court of Human Rights (ECHR) for a breach of Article 5(1) of the European Convention for the Protection of Human Rights and Fundamental Freedoms, the right to liberty and security. The Court had made clear that any such detention ought to be in compliance with the principle of proportionality and requirement for “absence of arbitrariness” and other less severe measures found to be insufficient to safeguard the individual and the public as in *Chabal v UK*. The Court also turned to case law on detention for mental disorders, *Winterwerp v Netherlands*, and alcoholism, *Witold v Poland*.

In *Winterwerp v Netherlands*, the court defined the conditions to be met for justifiable detention on the ground of mental health. The individual must be affected by an “unsound mind”, as observed by an objective medical expert, to be deprived of his/her liberty. The mental disorder must be specific to justify compulsory confinement and the validity of continued confinement depends upon the persistence of said disorder. In *Witold v Poland*, the applicant was taken, by police, after being allegedly intoxicated and behaving offensively. He was examined by a doctor and assessed as being “moderately intoxicated”, without any blood or breath tests, and confined in a centre for six and half hours. The applicant was awarded damage by ECHR as there had been violation of Article 5 s1. Intoxicated people, with conduct posing a threat to the public but not medically diagnosed as “alcoholics”, can only be taken into custody...
for protection of the public if less severe measures have been considered and found to be insufficient to safeguard public interest. A public health body, with statutory duty for disease control, should be able to have explicit criteria that the conditions are posing public risk, such as Public Health Act 1997 of the Australian Capital Territory. The Act has set out criteria for determining whether the conditions are liable to become a public health risk including:

- number of persons affected or potentially affected;
- actual degree or potential degree of public health risk;
- damage or offensiveness to community health standards;
- any reasonable precautions that the person with the risk might have or have not be taken to avoid or minimise the adverse consequences; and
- reasonable precautions that person at risk might take or might not have taken to avoid and minimise the effect of risks.

Public health regulations with high regard for safeguarding human rights, as emphasised by international conventions, can strike a balance between individual rights and public interest. There are explicit guiding principles to define public health risks and the law enabling restriction of individual freedom in specific circumstances. The public health policies are the rights of citizens to be entitled to health protection. The issues of human rights, in upholding health justice for infection control, must be proportionate, justifiable and reasonable. The universal health system should include early public health actions to protect the health of a population.

Health System During Pandemic

Prompt Public Health Action to Safeguard Population Health

Some governments have implemented preventive measures at an early stage to control massive outbreaks. Macau is close to mainland China, with heavy cross border travel. Taiwan is about 130 km from mainland China, with many Taiwanese living and working in the mainland and 2.7 million mainland visitors in 2019. The pandemic in Macau was much less significant than

42 Section 69 (2) (a) – (d)
43 Macao Government Special webpage against Epidemics”. Centre for Disease Control and Prevention, Macau (access 15 May 2020)
their neighbours’, such as Hong Kong, Korea and Japan. Macau and Taiwan had adopted a series of strict measures, since early January 2020. Prompt public measures, at any indication of a suspicious outbreak, with exponential increase, within a short period, and possibly leading to cluster outbreaks, were found to be effective in reducing infectious spread. The actions taken by Macao and Taiwan are described in Tables 2 and 3 respectively.

**Table 2 Public Health Measures for COVID-19 Infection Control in Macau**

- Macao, close to mainland China with heavy cross border travel, had the first imported case on 22 January 2020, and increased to 10 by 4 February, and no more new cases until 15 March, and the second wave flattened at the end of March.

- Government had adopted a series of strict measures, by cancelling all Chinese New Year celebrations, and anyone with fever symptoms should not leave Macau and it ordered 20 million masks for residents.

- All schools and universities were closed on 24 January and imposed border controls with temperature checks, health declaration and restricted opening time.

- Residents were not encouraged to travel to Wuhan, with tour groups suspended. On 27 January, all non-residents from or who had been to Hubei, in the past 14 days, were required to have a doctor’s note, certifying freedom from COVID-19, to be allowed entry.

- Government also declared the closing of several entertainment venues, such as casinos, theatres and night clubs.

- From 20 February, passengers coming from COVID-19 hotspots, needed to undergo medical checks upon entry and restricted entry from mainland China.

- The first wave settled very quickly by early February and second wave due to pandemic settled by end of March.

**Table 3 Public Health Measures for COVID-19 Infection Control in Taiwan**

- Taiwan is not a member of WHO and relies solely on her own efforts in formulating an action plan.

- The preventive measures started in early January and monitored all
individuals who had travelled to Wuhan within 14 days with fever or symptoms.

- Once the first case returning from Wuhan was identified, on 21 January, Taiwan had stepped up measures with 124 discrete action items, including border control from the air and sea, case identification using new data and technology, quarantine of suspicious cases, social distancing, educating the public while fighting misinformation, negotiating with other countries and formulating policies for schools and businesses.

- A mobile phone-based “electronic fence” was used as location-tracking to ensure people who are quarantined stay in their homes.

Although South Korea has not adopted drastic “shut down” measures, widespread quarantine measures and rapid testing have been effective in controlling the spread of infection45.

**Community Care System for Managing COVID-19**

Home management is appropriate for low risk patients with mild infections who can be adequately isolated in outpatient settings46. They can be managed remotely by general practitioners (GPs) with video consultation47 (Figure 1.1)48. Dyspnoea (shortness of breath) is a concerning symptom with no current valid tool to assess remotely, but measurement of respiratory rate, peak flow, oxygen saturation and observing for early warning symptoms (93% as cut off)49 may be helpful in clinical settings. Nurse practitioners and allied health professionals can help in home monitoring and coaching for self-management. Whole person care, of physical and psycho-social needs, for patients and families may be made available during the illness and recovery phase. The monitoring and coordination of care can be conducted virtually and on-site with protective measures.

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46 Supranotes 11, 12


49 Supranote 47 [Greenhalgh et al]
In Australia, the establishment of respiratory clinics, in primary care, led by GPs helped to keep potentially infected people away from other general practices and emergency departments, minimising the spread of infection\textsuperscript{50}. GPs were able to bulk bill phone or video consultations, to help contain the spread of coronavirus and eligibility for these services was expanded to specialists, mental health and allied health professionals\textsuperscript{51} to address any potential shortages of needed clinical services. Australia has developed online infection control training for 335,000 healthcare workers from primary care, aged care, disability services and hospitals.\textsuperscript{52} The primary care setting can help to identify “invisible cases” by more detailed analyses of probable cases at asymptomatic phase.

Apart from managing the acute phase, the primary care team would also convey advice on safety and monitor those living alone or unable to self-assess. The team would also act as a focal point of health resources, with consistent communication with the local community, to maintain general mental well-being\textsuperscript{53}. Despite isolation and physical distancing, the cases and involved family members can be well supported during this crisis. GPs, working with primary care providers, would act as health resource personnel in communities, an alternate source of care for patients with more stabilized conditions and facilitating self-management protocols, intensive coordination of care to meet the public’s psycho-social needs and close monitoring of vulnerable population groups.\textsuperscript{54}


\textsuperscript{51} Ibid

\textsuperscript{52} Supranote [Kidd]

\textsuperscript{53} Supranote 50 [Kidd]

\textsuperscript{54} Lee A, Chuh ATT. Facing the threat of Influenza Pandemic – Roles of and Implications to General Practitioners. \textit{BMC Public Health} 2010; 10:661 http://www.biomedcentral.com/1471-2458/10/661
**Socio-economic Factors for Infection Control**

Municipalities have a great potential to influence the social and medical environment of communities, ranging from informing the public on risk-reducing behaviours, managing the impact of stressors and accessing relevant and necessary goods and services such as housing, food and informal health care\(^\text{55}\). Inequality has enhanced the spread of COVID-19, such as the disproportionate infection rates of US African American populations\(^\text{56}\). The risks of infection and mortality are higher for individuals with underlying health conditions and the socioeconomically disadvantaged\(^\text{57}\). The response to COVID-19 cannot become successful without considering equity to mitigate health inequalities.

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\(^\text{55}\) Supranote 37 [Freudenberg et al]
Conclusion

COVID-19 has provided an opportunity to analyse rights to health from broader and more detailed perspectives. The rights to health should not be confined to access to conventional health services. The importance of appropriate public health measures and primary health care must not be underestimated. To deliver effective public health and primary care services, good governance and understanding of underlying socio-economic determinants are essential for better response and preparedness. The issue of human rights should consider public interests and rights to health protection in balancing the limitation of individuals’ rights. The principle of proportionality and “absence of arbitrariness” must be upheld to avoid abuse of power, to amplify the support of the common good by public health law.
ISRAEL
LEGAL AND ETHICAL RAMIFICATIONS OF COVID-19 IN ISRAEL

Jonathan Davies

Abstract: Since the outbreak of the corona pandemic, more than seven million people have fallen ill and about half a million people have died in approximately 200 countries. In Israel, the numbers have stabilized - to date around 17,000 infected patients by the virus, most of whom have recovered, and approximately 250 deaths. These low rates are related to the swift precautions the Israeli government enacted and the relatively young and low risk population.

The corona crisis affords a good opportunity of examining whether this will serve as an historical turning point. This article examines the pre-pandemic status of the health system in Israel to forecast what effect the Covid-19 crisis will have on human rights, in general, as well as on patient rights and ethical guidelines.

Two weeks after the outbreak, Israel transitioned from a normal functioning system and public, under a liberal democratic system of government and the civil freedoms upon which it is based, to a national state of emergency introducing regulations and appropriate orders within 14 days. This is perhaps characteristic of certain murky regimes to some, due to the state of lockdown and quarantine, barriers and road closures, mobile surveillance by the security services and social distancing constituting an infringement of basic constitutional rights: freedom of movement, the right to property, freedom of occupation, the right to privacy, freedom of information, freedom of religion and individual human rights.

1 WAML Governor for Israel, Former Editor in Chief of the “Medicine and Law” Journal (2000-2015), Former Chairman of the World Council of Presidents for Medical Law Organization (WAML), Represents injured parties in personal damage and medical malpractice claims. Email: davies@med-law.co.il
2 Based upon published information, the precise number of patients and deaths in China, is unknown.
COVID–19 caused a public health crisis with medical and ethical ramifications: it rewrote manuals of clinical treatment and brought a new condition with prognoses and symptoms with which physicians remain unfamiliar.

Despite the above, the Israeli health system did not make adequate preparations to diagnose and handle the current pandemic and its economic outcome. There is a shift from globalization and free trade to countries’ national debates concerning health v. economy that questions the influence of patients’ rights and the right to autonomy pre and post-advent of the vaccine.

Keywords: Pandemic; Public Health; Tests; Medical Dilemmas; Research; Treatment; Medical Directives Vaccinations; Ethical Ramifications; Human Rights; Public Interests

Introduction
The COVID-19 pandemic poses the most significant health challenge since the Spanish flu pandemic in 1918 and is the most influential economic incident since the 1929 Global Financial Crisis.

Israel has a solid health system that provides basic health services to all its citizens independent of their income, race or religion and more advanced private health services through private insurance provided by the health maintenance organization (HMO) funds. The population of Israel is to date 9 million citizens, a mostly young population which helped overcome the COVID-19 pandemic with very low numbers of casualties between mid-March and Mid-May of 2020. The significant economic effects have occurred and do currently still stand. This article will analyze the future legal and ethical ramifications of the COVID–19 on patient rights post-pandemic.

The present Corona pandemic (unlike other historical pandemics) is characterized by its extent and speed at which it spreads. This can be attributed to scientific developments in the era of globalization and freedom of information. It still seems that the complete data, resulting from the corona virus (the number of confirmed patients, the infections, those on ventilators and the number of deaths) relative to the size of the population, is perhaps less devastating when compared to historical pandemics. Its long term implications and the indirect damage to the future are more substantial than what could have been anticipated.
The March World Association for Medical Law Newsletter presented 5 short articles by prominent Israeli medical and legal academics, outlining the situation of the health system in Israel, as a provider of health services to all its residents, based upon fundamental principles of equality and access to health services. The arrival of COVID-19 has since altered much that was mentioned.

Guidelines of Scientific Research in Israel Prior to the Pandemic

Prior to the outbreak of the corona Pandemic, the Israeli health system was based on the National Health Insurance Law which provides a basket of health services and medical technologies to all its residents regardless of religion, race and gender. The Israeli decision-making process regarding public funding of new medical technologies is fair, transparent and evidence-based.

The scientific research was based upon principles of the Helsinki Declaration which mandated the obtaining of informed consent and adherence to a decision-making procedure, upon clinical trials with a safeguard of basic human rights and the distinction between adults and children participating in trials and medical research.

A wide range of medical experiments in Israel were conducted in various fields: pharmaceuticals and medical devices, products containing cells and tissues, epidemiology of diseases and more. Primary care in Israel has been fully computerized for thirty years. An enormous wealth of data is stored on the main frame computers of the four HMOs that insure all of Israel’s population.

The 1964 Helsinki Declaration can be viewed as a turning point in the recognition of modern patients’ rights. The Helsinki Declaration was adopted and incorporated into the Public Health (Experiments with Humans) Law in 1980 and since then procedures have been published focusing upon management of general research and the framework of the Ethics Committees.

3 https://www.worldometers.info/coronavirus/coronavirus-cases/
https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:04755a8b-7a08-432c-95b4-ag173113c796

4 Recommendations of the medical guidelines for obtaining informed consent in bio-medical research, that involves humans- were adopted at the 18th World Medical Conference in Helsinki, Finland in 1964 and were amended at the 29th World Medical Conference in Tokyo, Japan in 1975
of the Ministry of Health, hospitals, medical institutions and the HMO funds.\(^5\)

The Helsinki Declaration adopted the Geneva Declaration of the World Medical Association, which governed the relationships between doctor and patient provided as follows: “The health of my patient shall be my principal concern”, and the international codex for medical ethics declared that “any action or giving advice which might weaken the physical or mental durability of a human being, may only be used in his best interests”.

Other elements were simultaneously incorporated into the intimate doctor-patient relationship, which had an effect on the rights of the patient, such as the Ministry of Health, the HMO and the Insurance Companies, which, by means of regulation and internal directives, altered the fine balance between the doctor and the patient. The Medical Association which acts as the doctors’ guild came out against recognition of the autonomy of the individual and blamed the courts and attorneys for decisions against medical institutions, arguing that they contribute to “defensive medicine”.

The Protection of Legal Rights and Patient Safety in Israel

In the State of Israel, rights of the individual are governed in principle by a large number of legislative enactments which confer upon them a constitutional status from the Basic Law: Human Dignity and Freedom, enacted in 1992. This provides a constitutional effect to basic rights, such as: the right to privacy; the right to information; the right to property; freedom of movement; the right of health; and prohibition of discrimination. Prior to this, rights of the individual had been recognized in universal conventions, such as the Helsinki Declaration\(^6\).

As medical science and technology progressed, exciting new issues, along with the subject of patients’ basic rights, have arisen. Medical law is engaged both on the private and public levels, among which one can mention: the right to health services (through the health basket); the right of access to medical service in Israel and abroad; public health; national insurance; the right to medical information entered in the computerized medical records; remote

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5 The Ministry of Health has recently published an informed consent procedure in relation to trials involving humans whose applicability date of 20/5/20 will be deferred. [https://documentcloud.adobe.com/link/review?uri=urn%3Aaid%3Ascds%3AUS%3A05e ba217-fad8-4c79-89ff-cc9868c92c51](https://documentcloud.adobe.com/link/review?uri=urn%3Aaid%3Ascds%3AUS%3A05eb a217-fad8-4c79-89ff-cc9868c92c51)

medicine (telemedicine); medical confidentiality; medical negligence; the rights of children; handicapped people and the elderly, pregnancy and birth; sperm donation; surrogacy; termination of pregnancy; dying patients; trials involving humans; biotechnology and law; organ transplantation and trading in organs; fertility treatments; amelioration of terminal illnesses by means of cloning; implantation of genes in the patient’s body; and protection of genetic information.

Medical Law is governed by legislation and case law, transcending the boundaries of civil law, criminal law, family law, labor law, insurance law, administrative law and the laws of evidence.

Patients’ rights in Israel can be charted in the following five correlated circles.

**Charting of Patient Safety Rights**

- Protection of Patient Rights enacted to statutes in accordance with Human Rights patient safety and protection of specific population groups
- Protection of Patient Rights safeguarding the public interest enacted in statutes which protect Public Health and health services (HMO)
- Protection of the Patients’ Rights by sub legislation governing supervision and controlling standard of care in medicine, behavioral norms, and regulation.
- Protection of patients rights by rules of medical ethics in such as Helsinki committees. Termination of Pregnancy Committees, Institutional Ethics committees in various fields, and ethics disciplinary committees of the health professions etc.
- Realization of patient’s rights by means of compensation under the Medical Law Laws and, specific No fault compensation statutes (ringworm, polio, vaccinations, road accidents etc.)

The rights of the patient are closely correlated and derive their authority from the various legislative enactments and laws on the constitutional hierarchy ladder. When they conflict, it is a matter for the court to strike a balance between such rights, with proportionality and in accordance with the purpose of the statute.
The infringement of patients’ rights, in view of the repeated and changing swing of the pendulum from a liberal approach, which stresses the autonomy of the individual, to a paternalistic approach, where the State is prepared to sacrifice individual rights for the benefit of the public interest, has caused uncertainty towards the future.

**Coping with the Outcome of the Covid-19 Pandemic in Israel**

Since the COVID-19 outbreak, the State of Israel has been coping with the state of emergency, forced upon it by means of the publication of scores of emergency regulations and orders that have restricted the freedom of the individual and constitute an infringement of basic rights, such as the right to privacy, freedom of movement, freedom of religion and the right to property. Despite the declaration’s stated return to normality, the Government – with the support of the Supreme Court – has not withdrawn the state of emergency. It has left in place the emergency orders that are an infringement of the right to privacy and made this conditional upon them being enacted in principal legislation in the Parliament. The Supreme Court of Justice has approved the denial of individual rights, provided that the infringement occurs within the framework of principal legislation.

Since the pandemic was declared, the public discourse in Israel has been focused on patient count, examinations and ventilators, mathematical models, genealogical scenarios and medical directives. The medical teams have learned about this new disease with uncertainty while the treatment knowledge is drawn from unpublished scientific research, from accumulated intelligence of medical teams from overseas and consultations among the local medical community. Gaps in information, concerning the Covid-19 disease, have left data for interpretation and turned every relevant hospital into a patient treatment research and experimental center. Many different treatment protocols, emanating from various places worldwide, have been adopted and applied in the hospitals.

Another characteristic of the pandemic in Israel was public dispute, between specialists and public health experts, about how to handle the crises that challenged the Ministry of Health (MoH) directives to the public. This dispute has added to the uncertainty and the feeling that treatment has not been evidence based. For the first time in modern history, COVID–19 has caused deterioration in the absolute trust that citizens had in the health system while simultaneously increasing their praise for physicians as heroes of these challenging times.
What has not been Learned from the Previous Pandemics?

One of the complaints heard in Israel is that there should have been deployed a different plan to prevent direct and indirect damages that the COVID–19 pandemic caused and will cause in the future, including: excess morbidity (physical and the mental illness specially with the elderly); aggravation of the condition of chronic and oncology patients; and elective treatments, such as fertility treatments postponed as result of the closure of hospitals and outpatients clinics; the challenge to the status of the World Health Organization (WHO); and the status of the health systems unprepared for the pandemic and its economic disaster.

The Israeli government was flawed in its preparation for the pandemic, - emphasized by: lack of planning; lack of a clear policy; lack of emergency equipment (failure to equip medical facilities with ventilators); protective equipment; testing kits; reagents; and face masks, – it did almost immediately declare COVID-19 to be an infectious disease and was one of the first countries to lockdown its towns and cities and quarantine all those returning from abroad. These actions substantially reduced the number of infected public members. The health system was adept at isolating carriers and those who were ill and at risk of infecting healthy members of the population. The exit from the lockdown and preparedness for “the day after” was well arranged and orderly, to the extent that the number of victims is one of the lowest worldwide relative to the size of the population (9 million citizens)\(^7\).

Ethical Dilemmas of the Medical Community in Israel

The battle against any pandemic is first and foremost a race against time. This is especially true when one is concerned with an unknown virus for which there is no vaccine. The importance of time does not only pertain to halting the spread of the disease and coping with it on a systemic-strategic basis but is also concerned with the single patient and the course of the disease itself. Many doctors admit that the COVID-19 disease has surprised them and that it does not resemble anything encountered previously. The time factor and the push to find a solution has given rise to complex ethical dilemmas.

The urgent need for knowledge, about the Corona virus and its associated complications, is a factor that has led to doctors cutting corners and circumventing the usually accepted procedures of medical treatments

\(^7\) [https://www.worldometers.info/coronavirus/country/israel/](https://www.worldometers.info/coronavirus/country/israel/)
(diagnosis, examinations, treatment and prognosis), including obtaining approval of ethics committees when necessary. Despite the cooperation of the world’s scientific communities, doctors have quickly discovered that it is difficult to rely on the multitude of information previously published in the scientific literature. A notifiable feature of the Corona crisis is the enormous quantities of junk science published and disseminated.

Doctors’ working assumptions were that the only clinical expression of the disease is a viral infection of the lungs and that it is harmful, mainly, to the elderly and patients with pre-existing conditions, such as high blood pressure (57% of the patients), obesity (41% of the patients) and diabetes (37% of the patients). A change has occurred in understanding the disease and it has become evident that a multi-systemic clinical feature exists among Covid-19 patients, expressed in damage to the lungs, kidneys, heart as well as strong stomach pains, dermatitis, loss of taste and smell and even brain damage. In young people, there have been case reports of strokes involving the immune system and over-coagulation of the blood.

Ethical Issues of Publication and Peer Review

With the need to find a quick solution, ethical considerations became secondary. Generally, medical opinion is based upon facts (evidence-based medicine). Many articles published during this time had an influence on the understanding of the disease and its treatment. This has subsequently been the subject of criticism - owing to doubtful methods of research, lack of suitable inspection of groups, publication of conclusions with wide implications based upon a very limited group of patients and without a peer review process.

The Debate over the Diagnostic Effectiveness of PCR Tests

Polymerase Chain Reaction (PCR) tests are the main tool for the diagnosis of corona worldwide, but these tests have two critical limitations: the PCR test provides a picture of a situation only relevant in terms of the moment that it was carried out (a negative answer received on the day of the test will not necessarily be valid on the following day); and relates to the reliability of the test, estimated at only about 70% accuracy.

These limitations have posed some disputes and dilemmas for doctors. Should a patient, suffering with corona symptoms, be hospitalized in COVID-19 special wards or a regular ward? The decision should be made based upon test results but these are not always consistent and sometimes even contradictory in nature.
As the crisis progressed, the health system was forced to find medical solutions for the unclear situation: it began by carrying out additional tests, including antibody tests (serological tests); and bronchoscopy tests (a procedure that enables the taking of samples of liquids from deep inside the lungs). Some hospitals set up special purpose wards for suspected corona patients whose diagnoses were yet incomplete. Those who arrived from abroad were quarantined in special hotels that were opened specifically for the pandemic. It took some time until tests were applied in old age homes and figures show that most casualties were elderly patients.

The lesson learned from other countries was to apply the triple T policy (Test, Trace, and Treat). There is still dispute between researchers as to the effectiveness of the triple T policy and its scope. Tests that doctors are proposing to use to diagnose the disease could possibly be unnecessary for some of patients.

**The Race to Acquire Ventilators**

Since the beginning of the outbreak, it was obvious that it’s most striking and substantial feature was a serious lung disease. The lack of ventilators led to the general recruitment of the health system and the Intelligence Forces to import thousands of ventilators. It also led to local production of ventilators by companies with no prior experience in the manufacture of medical equipment. The technical specification of the ventilators was based upon the assumption that, in some of the cases, breathing support would be necessary for a prolonged period of two or more weeks, but it quickly became evident that this assumption was not correct and in severe cases some of the patients required support of an “ACMO” system (an artificial heart-lung machine). At the beginning of the outbreak, there was relief based upon the information coming from Italy: that it would be worthwhile to ventilate the severe patients as quickly as possible but cumulative clinical experience, of treating Corona patients, showed that there was no need to be in a hurry to use the invasive ventilation methods. It became evident that the number of patients requiring the ventilators was less than expected. This highlights that treatment of the disease was given in the absence of evidence based medicine (EBM).

Another argument, that in the event didn’t need to be realized, was the prioritization of the use of ventilators for severe patients and its ethical implications. The MoH set up an ethical committee that published its recommendations during the crisis but the Israeli health system didn’t need to be challenged by these ethical dilemmas.
Treating Covid-19 Patients with Non-Approved Medications

According to the Pharmacists (Preparations) Regulations, a drug will be registered in the State Register of Medicines only after its safety, efficacy and quality have been proven. The decision to register a drug is made after the information submitted has been thoroughly and critically examined. The registration department establishes the policy on registering drugs containing new substances, authorizing generic drugs and rules for restricting drugs. The Medical Device Division deals with the licensing and supervision process for all types of medical devices and equipment, including rehabilitation and mobility devices.

COVID-19 was treated with medications supplied in the absence of prior information, some on an experimental basis. The information and experience, related to this disease, mostly has been scant. The use of certain medications has been recommended and in many cases the treatment procedures have changed “on the move”. The problem was that insufficient data existed as to the efficiency of the medications and it was necessary for every medical center to formulate its own treatment protocol and to determine what procedure to follow for a patient in a moderate to severe condition. From the very beginning, there were unestablished procedures based upon unsubstantiated research. It has not been possible to ascertain the effectiveness of the medications.

Telemedicine as a Primary Clinical Tool?

Telemedicine treatment has developed considerably in recent years and has become an acceptable form of communication between doctors and patients and between medical professionals to bridge any information gaps. The COVID-19 pandemic has accelerated the necessity for telemedicine to overcome problems of the need to access medical services whilst maintaining distance and without eroding doctors’ abilities to carry out clinical tests successfully, without infringing the patient’s autonomy and rights. The Ministry of Justice published guidelines for doctors to receive consent to medical treatment and lawyers to receive power of attorney and to access of medical records that apply temporarily for the emergency period. The use of communications, by means of ZoomTM, became very popular and these practices may apply permanently.

The Race for Vaccinations and what will happen then?

Prior to COVID-19, any person who suffered a major medical crisis, such as life threatening medical procedures, had a full choice to refuse to be admitted
to the hospital, even when the alternative was a serious jeopardy to his/her life. Any person or parents who refused to vaccinate themselves or their child had the right to refuse treatment, as long as their refusal didn’t harm public health.

Israeli policy makers voted against mandatory vaccination and allowed Israelis to choose and decide according to their individual.

The global race to find a vaccination calls for special attention to what will happen once the vaccinations are developed and applied worldwide. In some societies, vaccination is mandatory with only a few exceptions (medical, religious). Based on the right to autonomy, Israel did not apply a mandatory vaccination policy even when there was an outburst of measles.

It is presumed that, once a vaccination is found, the above paternalistic policy will apply in accordance with the public interests and vaccination will become mandatory.

**Ramifications of the Covid -19 on Patients’ Rights**

The rights of the individual have been put on hold and are subordinated to the public interest. The rights of access to medical services to which normally there is no challenge, are being subordinated to the public interest under emergency orders which require people to remain in isolation. Owing to uncertainty, regarding the side effects of the COVID-19, the rights of the patients are being infringed. If this means that the medical manuals are being rewritten, then the legal books must also be reexamined. There are also questions about the rights of a person who views him/herself aggrieved, by reason of a decision of the government to introduce a lockdown, thus preventing him/her from exercising a basic right of freedom of occupation. (S)he cannot challenge the administrative decision, in accordance with the principles of administrative law or employment law. This also applies to a person who is suffering from a chronic disease and who, as a result of the spread of Corona, is unable to obtain proper and adequate treatment. Pursuant to patient safety statutes⁸, (s) he’s entitled to remedies. If this forecast is realized and the rights of the patient have been subordinated, to the general public interest, (s)he probably will not be entitled to compensation.

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⁸ Section 5 of the Patents’ Rights Law requires health system to provide patients with adequate and reasonable quality health services
The answers to these questions are quite simple. Where a constitutional right has been infringed, the court will examine the proportionality of the infringement, striking a balance between the competing interests (the public interest and the personal interest) and if the infringement is disproportionate, the decision will favor the citizen. It also applies under the Civil Wrongs Laws, should the claimant have suffered damage, the source of which is negligence or a breach of statutory duty which could have been prevented, the competent court will compensate the injured party, pursuant to the degree of compensation and according to the amount of proven damage.

These examples reflect a changing trend, resulting from the COVID-19 pandemic, which has shifted the point of balance from the protection of rights of the patient towards a recognition of the public interest, as possessing greater weight. As the pandemic has not yet completely subsided, it is difficult to predict the future. Where doctors are treating a still unknown disease, the rights of the patient to, which one has become accustomed, such as: the right of informed consent; the right to make free and autonomous decisions; the right to refuse medical treatment; the right of access to medical treatment; freedom of movement; and freedom of occupation, are changing in front of our eyes and will be influenced by the outcome of the pandemic.

**Conclusion**

The health system in Israel, in common with those worldwide, did not make adequate preparations to diagnose and handle the current pandemic and its economic outcome. In the short time, since the outbreak, there has been a shift from globalization and free trade to national debate of the public interest health v. economy and how this will influence patients’ rights: the right to autonomy and other ethical considerations.

Each country will make its decisions, balancing probabilities in terms of cost-effective damage (direct and indirect) that it has sustained in the battle against COVID-19. The major question arises as to whether it would have been possible to prepare differently and to prevent the heavy economic damage that will occur to the national economy as a result of the failures to prepare and anticipate the crises.
The question raised in the article is how will the pandemic’s medical and ethical turbulence take control of the legal discourse and whether, in the name of the public interest, the pendulum will swing back to its natural position and whether the authorities (the legislative, the executive and the judicial branches) will take advantage of the situation to erode the rights of the individual.9

In normal times, these methods would be dismissed as patently illegitimate. They are now retrogressive vis a vis the right to life and physical perfection.10

It is assumed that public health interests will prevail over the right to autonomy in Israel and worldwide and the obvious example will be that, once a vaccination will be found, the above paternalistic policy will apply in accordance with the public interests and vaccination will become mandatory.

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9 [https://documentcloud.adobe.com/link/review?uri=urn:aid:scds:US:02659468-ff2c-4408-8e08-0455aa0a0df](https://documentcloud.adobe.com/link/review?uri=urn:aid:scds:US:02659468-ff2c-4408-8e08-0455aa0a0df)

10 Supreme Court of Justice Petition 2435/20 Yedidia Leventhal, Advocate v. The Prime Minister and others (published in Nevo 7/4/2020)
JAPAN
JAPANESE GOVERNMENT POLICY ON COVID-19

Mitsuyasu Kurosu*

Abstract: On January 16 2020, the first case of COVID-19 in Japan was a man with Chinese Nationality who travelled to Wuhan. Since then, infected cases have continued to increase and the prime minister issued an emergency declaration on April 7. The features of the Japanese government’s measures, against COVID-19 are 1) outing restriction by request, not by order, 2) limiting polymerase chain reaction (PCR) testing and 3) responding to passengers on a cruise ship at an early stage.

The reasons for the delay, in the development of the medical system for COVID-19, are as follows: since medical personnel are busy with normal patient care every day, there were few hospitals that could accommodate COVID-19 patients; financial support for hospital infection control including for medical staff was insufficient; and recent medical cost reduction policies have reduced the numbers of hospital beds and doctors and delayed ICU maintenance.

In-hospital infections of COVID-19 have occurred in some medical facilities, including university hospitals. A cause of some of them was the lack of disinfectants and masks. It has become necessary to stockpile such medical materials and to switch their production from overseas to domestic.

Predicting the 2nd and 3rd waves of COVID-19, will be required, to respond for a long time on an annual basis. Guaranteeing the basic human rights of individuals, such as freedom and control in those rights for public welfare policy, continue to be a challenge. Enhancing laws and regulations is important. Improving the ethical consciousness of each individual citizen’s consideration for the society and others will lead to an appropriate judgement.

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Keywords: COVID-19; Japanese Government Policy; Outing Restriction by Request; Limiting PCR Testing; Passengers on a Cruise Ship; Lack of Medical Materials; Appropriate Judgement

1. INTRODUCTION

On January 16 2020, the first case of COVID-19 in Japan was a man with Chinese nationality who travelled to Wuhan. Since then, the number of infected cases has continued to increase and the prime minister issued the Declaration of a State of Emergency on April 7. Although it continued to increase, the number of infected cases, per day, reached the maximum (720 cases) on April 11 and has decreased since then. On May 24, there were 42 cases. On May 25, the Declaration was lifted in all prefectures, as it was deemed that the emergency measure was no longer necessary. Clusters of COVID-19 have since occurred in several areas, hinting at a second wave.

The COVID-19 issue has a huge impact, not only on industry and economy, but also on education, sports, arts and research fields. The traditional social life is under pressure of change. The features of the Japanese government’s measures against COVID-19 are: outlining restriction by request, not by order; limiting polymerase chain reaction (PCR) testing; and responding to passengers on a cruise ship(s) at an early stage. This article mainly examines the government’s countermeasures against COVID-19, related to medical care, human rights and law.

2. Regarding Laws and Regulations-Restrictions on going out by Request

On February 7, the government designated COVID-19 as an infectious disease, in accordance with Article 6 of the Act on Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998, Infectious Disease Act). Governmental regulations have added restrictions to access buildings, blockades, traffic restrictions, quarantine and progress reports by prefectures.

The amendment of the Special Measures Law against New Influenza (hereinafter referred to as the Special Measures Law) was enacted on March 13 and became effective from May 14. It was also applied to COVID-19 and it became possible to issue an emergency declaration. The authority, to issue actual requests and instructions, lies with the prefectural governor in the area where the emergency declaration was issued. This declaration is made only
when there is a risk that the medical supply system will fall into the danger of collapse and, even if it is not issued, the prefectural governor can implement measures based on the action plan set in advance.

The government’s action plan stipulates that, if basic human rights are respected and restrictions are placed on the rights and freedoms of the people, these restrictions shall be the least possible. The government says it has made a request to avoid restraining private rights, such as basic human rights, as much as is possible. It can be said that the government wanted to lower the level of salary compensation, due to absence from work, requesting instead of decreeing it.

The choice between a compulsion with penalties, compulsion without it or just a request will depend on the people’s acceptance and cooperation with requests. Whether anything is going to be stipulated by law and trust in the government will both be relevant. In the case of a request, the ethical standards are to be asked of each citizen.

it is appreciated that Japan’s request policy was reasonable. It is necessary to be vigilant and take measures against the second and third waves in the future. Each citizen will be asked whether (s)he will obey the restraint of going outside because of the law or will (s)he accept same autonomously as an ethical decision, respecting a consideration of others and society.

3. Medical Treatment-Suppression of PCR Test

In the early days of the outbreak of COVID-19, immigration control policy, from infected areas, was taken at the waterfront when entering Japan, such as for airplanes and ships entering from overseas. Afterwards, small-scale clusters began to occur and the government’s task force was changed to address cluster measures on February 25. The PCR test was to be performed only when it was deemed necessary by the doctor and the tests’ analysis would include private laboratories, such as the regional health research institutes and quarantine stations. The PCR test, in public institutions, could not keep up with the demand, due to lack of staff and the government’s approach to increasing staff and utilizing private inspection institutions was weak. The number of people tested by PCR, from February 6 to May 31, was 244,824, which was about 2110 people per day: 16,650 people were positive and the positive rate was 6.8%. The use of PCR tests in Japan was low, compared to other OECD countries.
Why was it at a low level? The government was working to increase the number of PCR tests, while maintaining a medical system that accepts positives. Otherwise, it would lead to a collapse of the healthcare system. The improvement of the medical system was not simple. The government was reluctant to increase the number of PCR tests. The reasons for the delay in the development of the medical system are as follows: medical personnel were already busy with normal patient care every day and there were few hospitals that could afford to cure COVID-19 patients; financial support for hospital infection control, including medical staff, was insufficient; and recent medical cost reduction policies reduced the number of hospital beds and doctors and caused delays in ICU maintenance.

The Medical Association decided to establish its own PCR laboratory in response to such governmental measures. The future should combine the PCR with the antibody tests and recommend hospitalization or at-home treatment according to the symptoms.

4. **Response to a cruise ships,”Diamond Princess”**

On February 3, a cruise ship, called “Diamond Princess”, carrying 2666 passengers and 1045 crew members, was looking to dock at a destination. The Japanese government permitted the entry of the “Princess”. There was no facility that could accept more than 3000 potentially infected persons.

Quarantine started on board, on February 5. It took 14 days for the quarantine to finish, due to the inadequate system of quarantine of unknown infectious diseases and PCR testing, with quarantine officers being infected. All passengers were able to disembark on March 1, about one month after entering the port: 712 passengers were infected and 13 passengers were deceased.

5. **Factors leading up to just before the crisis of medical collapse**

The government has continued to adopt neoliberal policies in recent years. As a result: the number of public health centers that were busy dealing with new corona infected people decreased by 40%; the policy of controlling the number of doctors caused the number of doctors per population to be 50% of that in Germany; medical cost reduction measures kept medical fees low, putting hospital management in a difficult situation and regular medical examinations busy; and the reduction of numbers of beds inevitably limited the available beds for COVID-19 patients.
In conclusion

In-hospital infections of COVID-19 have occurred in some medical facilities, including university hospitals. A cause of some of them was the lack of disinfectants and masks. Disposable items were repeatedly used several times. It became necessary to stockpile such medical materials and to switch their production from overseas to domestic.

Predicting the 2\textsuperscript{nd} and 3\textsuperscript{rd} waves of COVID-19, will be required to respond for a long time on an annual basis. Guaranteeing the basic human rights of individuals, such as freedom and control in those rights for public welfare policy, continue to be a challenge. Enhancing and adapting laws and regulations are important. Improving the ethical consciousness of each individual citizen’s consideration for the society and others will lead to holistic and national appropriate judgements.

References


2. Basic Policies for Novel Coronavirus Disease Control (Revised on April 7, 2020) https://www.mhlw.go.jp/content/1090000/000620733.pdf

3. This law incorporates the Tuberculosis Prevention Law and the Sexual Diseases Prevention Law and the AIDS Prevention Law, along with the abolition of the Infectious Diseases Prevention Law. A pandemic of SARS occurred in 2003 mainly in East Asia, but no case of occurred in Japan. Then, in 2009, a large outbreak of the influenza virus HINI occurred in Japan. The governor requested that citizens refrain from going out, but at that time there was no law regarding that request. Therefore, in 2012, the Act on Special Measures against Pandemic Influenza, etc. was enacted, enabling requests based on the law.


5. For example, you can get the plan of Tokyo can be obtained from the following site (in Japanese). file:///C:/Users/kurosu%20mitsuyasu/Desktop/東京都新型インフルエンザ等対策行動計画.pdf
6. National Action Plan for Pandemic Influenza and New Infectious Diseases

7. Nakamura discusses non-compulsory measures such as restraint of going out in Japan at the following site. (in Japanese) https://www.spf.org/iina/articles/nakamura_03.html

8. This number excludes returnees from the “Diamond Queen” cruise ship and charter flights. And there were 16650 positive people and the positive rate was 6.8 % https://mainichi.jp/covid19

9. Positive people will be admitted to the hospital or stay in an accommodation facility as follows, depending on the doctor’s judgment. (in Japanese)

① Admission to hospitals that can appropriately manage infections, such as designated medical institutions for infectious diseases

② Stay and health observation at an accommodation facility operated by Tokyo, etc. in order to prevent infection to family members

10. As of April 20, there were more than 11,000 dedicated beds for corona patients and more than 6,600 hospitalized corona patients. It was 6 prefectures where more than 80% of the beds were filled. More than 1700 people with mild illness were treated at hotels and homes. (in Japanese) https://www3.nhk.or.jp/news/special/coronavirus/medical/
NETHERLANDS
WHAT IS THE ROLE OF THE EUROPEAN UNION IN THE COVID-19 PANDEMIC?

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Abstract: Whereas the heart of the purpose and activity of the European Union is concerned with economic harmonisation, its internal market, and the freedom of movement of people, goods, services, and capital, necessarily require public health measures. The EU is committed to both human rights and to “Health in All Policies”. This paper considers how that agenda has been confronted by the COVID-19 pandemic. It considers how the EU Treaties limit the possible scope of that response. The paper considers responses in relation to freedom of movement, the work of the European Centre for Disease Prevention and Control, issues relating to the operation of the General Data Protection Regulation, and the Clinical Trials Directive
and Medical Devices Directive. It concludes with a brief examination of the economic responses of the EU to the COVID-19 pandemic. An Appendix gives a brief introduction to EU (health) law and history.

Keywords: EU; COVID-19; Public Health; ECDC; GDPR

Introduction

The European Union (EU), with its central objective of creating an internal market, with free movement of people, goods, services and capital across the Member States’ borders,¹ and, with its Treaty-based competence to bind its 27 Member States through legislation and coordinated soft-law responses,² is where one might expect to see robust, harmonised, collective action in the face of the current global COVID-19 pandemic. With its broader commitment to human rights, especially in the Charter of Fundamental Rights of the EU, one might expect to see measures to ensure equality of access to health care for all the EU citizens. Elements of the EU response to COVID-19 have worked well, particularly the European Centre for Disease Prevention and Control (ECDC) Early Warning and Response System (EWRS), with the ECDC alerting the Member States to the threat, on the basis of aggregated information.³ The EU took measures to ensure the availability of medical equipment through the rescEU programme, within the EU Civil Protection Mechanism,⁴ and measures to ensure the supply of medical equipment.⁵ In February and March 2020, the EU response was limited, as the infection and death rates rose in the different Member States.

¹ Article 3(2) Treaty of European Union (TEU), and Article 26 Treaty on the Functioning of the European Union (TFEU).
² TEU and TFEU
³ The European Early Warning and Response System EWRS opened an alert notification on January 9 2020 informing ECDC and all member countries; on January 28 the EU Civil Protection Mechanism was activated; this compares to the official notification of China to the WHO China Country Office on Dec 31 on increased numbers of cases of pneumonia of unknown etiology; WHO reported on Jan 5 a disease outbreak news. See, https://www.ecdc.europa.eu/en/early-warning-and-response-system-ewrs; https://www.ecdc.europa.eu/en/covid-19/data-collection. Indeed, the EWRS worked so well, that (Brexit) UK wants to stay connected: https://www.theguardian.com/politics/2020/may/02/uk-seeks-access-to-eu-health-cooperation-in-light-of-coronavirus. (Each last visited 13 June 2020.)
The impact of COVID-19, so named by the World Health Organisation (WHO) on 11 February 2020, and characterised as a pandemic by the same on 11 March 2020, has been relatively rapid; it emerged in China in late 2019 and spread globally in the early months of 2020. This virus and disease are part of a family of Severe Acute Respiratory Syndrome (SARS) that has long cast a global shadow and produced particular incidents for years. The pandemic tested the preparedness of established policies and provision. This paper, written in the midst of the pandemic in Europe, considers elements of the preparedness of the 27 EU Member States in the collective, harmonising action of their Union. It addresses what is in place and answers why other things, one might expect to see, are not (yet) in place. It differs from the papers that explain the responses of individual nation States, since the Member States of the EU do not cede all their sovereignty to the EU and its political institutions; the EU is not a single, sovereign State. As public health and “health in all policies and activities” (HiAP) are key concepts in the EU and in its Treaties, it is legitimate to ask - as many EU citizens may well do - where is the EU response in the COVID-19 pandemic?

The paper considers the place of health in the concept of the EU. The EU has limited legal competence in relation to health, which explains the limits on the response to the pandemic. It evaluates where the EU has acted in relation to the pandemic. It examines freedom of movement, the ECDC and the regulatory regimes for the protection of personal data, clinical trials and medical devices. It relates these to the Charter on Fundamental Rights of the European Union, in the face of the pandemic, rights to free movement, to access medicines and devices and to privacy. Rights to life and health care require an economic base and the final part of the paper briefly considers the EU’s efforts to protect the future economic life of the Union.

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8 Articles 9 and 168(1) TFEU.

9 We include a short appendix on EU history and law, which may be useful to contextualise this first part of the paper.

10 See in particular Article 6(1) TEU.
Understanding the Mandate for (Public) Health in the EU

The EU is not equipped or legally competent to deliver frontline health care or to address systemic differences in health care delivery between its Member States. The EU pursues the Treaty-based duty to ensure “Health in All Policies”. Whereas Article 168 creates EU competence in relation to public health responses, the responses are limited because, by Article 168(7), the Member States have retained sovereignty for the organisation and delivery of their national health systems:

“Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.”

This is in line with the right to health care, created in Article 35 of the Charter of Fundamental Rights of the European Union: “Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities” (emphasis added).

This means two important things, in relation to the EU response to the COVID-19 pandemic: the EU has no authority to centralise the response; and it has no infrastructure to centralise the response. The EU cannot command the Member States’ healthcare professionals or infrastructure (such as doctors, nurses and hospitals) to produce a harmonised response. EU participation in relation to health is about facilitating cooperation and promoting health amongst the Member States.\(^\text{11}\) Its focus is in soft-law measures, rather than in creating major legislation to create centralised healthcare provision.\(^\text{12}\)

This is demonstrated in the legislation that relates to the availability of healthcare in relation to the exercise of freedom of movement within the

\(^{11}\) On the basis of Article 6(a) TFEU, the EU has a competence to perform actions to support, coordinate or supplement the action of the Member States, and the areas of such action shall at European level be ‘protection and improvement of human health’. There are also several opportunities in Article 168(2) and 168(3) TFEU.

EU. Regulation (EC) No. 883/2004 which coordinates entitlement to social security benefits accrued in Member States, by citizens moving between Member States, enables citizens to gain emergency healthcare whenever they are temporarily staying in another Member State from that where they reside. Provided that a prior authorisation is granted by the competent institutions, Regulation (EC) No. 883/2004 also allows citizens to seek planned healthcare in another Member State, from the one in which they have accrued entitlement to the care where it cannot be provided in a timely manner. Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare, enables citizens to seek planned healthcare in Member States other than the one in which they have affiliation in the health system (namely where they have purchased their health insurance). The Directive makes this a matter of right for out-patient care and a rebuttable presumption of permission for in-patient care. For both the Regulation and the Directive, the care that is sought outside the Member State where one is linked by insurance contract can only be what one is entitled to by that insurance (it has to be in the basket of goods that you have purchased). It is subject to the broader issues of the restriction of free movement to ensure a “lockdown” and that is determined individually by each of the 27 Member States, as a matter of their sovereignty. These instruments also indicate that non-medical, social care is largely beyond the purview of the EU. This lack of decisive legal competence for the EU is particularly difficult in the face of human rights concerns. Older people and people with disabilities may be discriminated against by new Covid-19 intensive care guidelines, suggesting that their rights, as patients, may be at risk of violation. One might have hoped that the EU would be a place to challenge these national policies.

Whereas the EU Treaties and policies have created soft-law mechanisms of guidelines and health promotions that operate to ensure a smooth functioning, freely moving citizenry in the general life of the EU, in the extraordinary emergency situation of this pandemic, the EU has very little authority or infrastructure to operate at the frontline of healthcare. This explains the scope of the response.

13 Regulation (EC) 883/2004, Articles 19 and 20, respectively.
The Immediate, Direct Response.

There are a number of direct measures that the EU has taken in response to the pandemic. One set relate to the freedom of movement, the other to the surveillance, control and prevention of the disease.

The Freedom of Movement

From March 2020, the EU put in place a number of measures concerning the modification of freedom of movement to respond to the Coronavirus and Covid-19. This was not about locking everything down and ensured the continued movement of goods, including Personal Protection Equipment (PPE), between the Member States. The continued possibility of movement of healthcare professionals between Member States to meet local needs is desirable. The EU acted to repatriate citizens. However, non-essential travel was restricted, largely by the actions of the Member States.

The freedom of movement of individuals is a challenge to their fundamental rights. Free movement of EU citizens is a right, under Article 45 of the Charter of Rights of the European Union. This is not an absolute right: under Article 52, Charter rights can be limited in their scope, proportionately, to meet “the need to protect the rights and freedoms of others”. The temporary closure of external borders, in an acute international health crisis that has been declared by the respective international competent authority, does not necessarily constitute a serious conflict with fundamental rights, especially as the EU supported actively, and in collaboration with Member States, the repatriation of stranded citizens, both its own (EU) as well as ex-pats. EU law allows the restriction of entry into the EU to respond to public health threats, linked to the International Health Regulations (IHR) definition of epidemic. Signatories of the IHR have agreed to the common criteria, process and procedures to keep

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15 Free movement of professionals in relation to health is somewhat tempered by the Member State’s residual right to ask about the content of the studies undertaken to achieve the professional qualifications in relation to healthcare. See Directive 2005/36/EC as amended by Directive 2013/55/EU. The response during the pandemic has been to encourage the acceleration of this process.


17 See Reg. (EU) 2016/399, particularly Article 2(21); Directive 2004/38/EC, particularly Articles 1 and 29.

the consequences of the containment measures to the absolutely necessary limits. It is the nature of an “unknown” pathogen for which, in the early state of an outbreak, many mechanisms are unclear and precautions might be more rigid, than one would apply in the later stage, with better knowledge. The current reality of excess mortality is an indication that there was, and is, a severe health threat that falls under the IHR. Is this an unjustified infringement of individuals’ rights? Were the measures limited to the absolutely unavoidable restrictions (being proportionate) or were they in excess? It is too early to answer this question comprehensively.

The temporary closure of internal borders is a different issue and would need to be seen against the EU’s principal of free movement. The restriction of free movement of people is allowed under EU law, but this is more complex. This is not the first time that some of the internal borders were closed and some preceding events had less plausible justifications. The same view applies regarding the IHR as the Member States are the signatories and have not delegated the health authority to the EU. Through the entire process, the EU has pressed Member States to allow cross-border workers to commute to their workplaces, to find solutions for seasonal workers and to allow the movement of goods - to keep the restrictions at the lower limit.

Another question is the consequences of individual Member States restricting cross-border movements for the EU cross-border mechanisms and regional cross-border collaborations. The decisions to close borders have overruled regional agreements on cross-border collaboration (such as, the joint hospital at the Spanish-French border; pooling inter-hospital-tranfer resources and use of intensive care units (ICUs) in the Aachen-Maastricht-Liege region; sharing infrastructure by communities on either side of the German-French border). Some of these cross-border agreements were especially intended to improve resilience of the regions in crisis situations but, in a real crisis, these agreements are not robust and the decisions relating to closure of borders (especially in

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19 See Reg. (EU) 2016/399, particularly Article 2(21); Directive 2004/38/EC, particularly Articles 1 and 29. See DG Internal Policies, Policy Department C: Citizens’ Rights and Constitutional Affairs. 2016 Obstacles to the right of free movement and residence for EU citizens and their families: Comparative Analysis PE 571.375 European Commission. http://publications.europa.eu/resource/cellar/29524abc-9ad1-11e6-868c-01aa75ed71a1.0001.03/DOC_1 (last visited 13 June 2020). It is worth noting that there is also a possibility to restrict the movement of goods (at the external or internal borders) to respond to public health threats under the TFEU, Article 36. It is clear that the right to freedom of movement is not an absolute right in EU law.
areas with cross-border arrangements) will have to be judged on the basis of the proportionality of the response to the risk. The same reflection will be required for the restriction of the right to move across borders to receive health care that is not provided in a timely manner (relative to the prognosis and condition of the patient) under Article 20 of Regulation 883/2004.

**The European Centre for Disease Prevention and Control**

The ECDC and EWRS are important parts of the EU response to the pandemic.\(^{20}\) ECDC started operating in 2005.\(^{21}\) It is an independent Centre, but it does not have the higher legal status of the European Medicines Agency or the European Food Safety Authority. The mandate for the ECDC is “to enhance the capacity of the Community and the Member States to protect human health through the prevention and control of human disease, the mission of the Centre shall be to identify, assess and communicate current and emerging threats to human health from communicable diseases.”\(^{22}\) In terms of the current COVID-19 pandemic, it is important to see the scope of the work of the ECDC.

“Within the field of its mission, the Centre shall.\(^{23}\)

(a) search for, collect, collate, evaluate and disseminate relevant scientific and technical data;

(b) provide scientific opinions and scientific and technical assistance including training;

(c) provide timely information to the Commission, the Member States, Community agencies and international organisations active within the field of public health;

(d) coordinate the European networking of bodies operating in the fields within the Centre’s mission, including networks arising

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from public health activities supported by the Commission and operating the dedicated surveillance networks; and,

(e) exchange information, expertise and best practices, and facilitate the development and implementation of joint actions.”

Member States have obligations to provide information to the ECDC on relevant technical and scientific matters, information provided to “the Community network via the early warning and response network”, and identify “recognised competent bodies and public health experts” who could contribute to the work of the ECDC.24

ECDC has duties in relation to the surveillance networks of the Member States’ Competent Bodies, and the Network created by the EU in 1998. These extend to quality control, cataloguing activities, communicating results of analyses, and creating harmonised methodologies.25 Article 5(3) is particularly telling about the nature of the ECDC:

“By encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes.”

The ECDC provides “independent scientific opinions, expert advice, data and information”26, the “early warning and response system” (EWRS),27 and “scientific and technical assistance and training.”28 The Centre also has a duty to report on emerging health threats to the EU and Member States, through data gathering and analysis in collaboration with the Member States.29 The budget to achieve all of this work is small, especially when compared to the funding allocated by Member State governments to their national agencies.30

In terms of the Coronavirus pandemic, the ECDC work has been through the EWRS and in publishing, since early January 2020, technical guidance and technical reports, on risk and response strategies, in relation to the virus and disease.\(^3\) It also includes surveillance and aggregating information, at EU level, and addressing strategies for dealing with the virus and disease, in relation to hospital facility preparedness, the needs for personal protection equipment, social distancing and, most recently, contact tracing.\(^3\) It has contributed to the understanding of the pandemic and to the development of health education for the general population and for policy-makers and regional and local healthcare managers. It is providing coordination for information for testing laboratories (on the nature of tests and also on where such laboratories are situated in institutions across the EU/EEA). Whereas there is some provision for emergency in-the-field response through the ECDC, this is for small-scale deployment outside the EU (in developing economy countries); in-the-field response within the EU is by Member States. Where there has been sharing of resources, between Member States, it has been largely on a bi-lateral level, between individual Member States. Perhaps one question that will be raised, particularly by the less economically developed EU countries, is how far the ECDC should develop a resource-sharing response facility, to coordinate shared public health delivery across EU Member States.

Conclusions that might be drawn about the ECDC are that it needs strengthening. With indications from the WHO that the Coronavirus and Covid-19 problems will take years to control\(^3\) and that a vaccine or drug therapy is some way off, the measures that ECDC provide for the EU and beyond are crucial. One might see an argument for both greater funding, and a strengthened legal status for this agency. There is no strong argument to support the centralisation of laboratory (lab) resources or to create other similar infrastructures. Decentralised lab capacities, for testing, and different research groups working on vaccines, seem to have greater potential. The ECDC must have clear authority in harmonising case definitions and harmonising case reporting, authority to define the minimum requirements for a comprehensive European surveillance infrastructure and network including the real-time and unfiltered access to the surveillance data from all Member States and the authority to recommend

and coordinate containment strategies once more than one Member State is affected by an outbreak, including the authority to recommend and assess regional strategies, independent of national borders.

**EU Legislation to Support Privacy and Access to Health Care**

Responses to the Coronavirus pandemic must include a vaccine and other pharmaceuticals that seek to alleviate the symptoms or cure the disease. Politically, the EU has contributed enormously to the international effort, particularly through the Global Pledging Summit, and pushing for a major WHO resolution, to respond to the pharmaceutical challenge.\(^{34}\) Surveillance and monitoring of the rate of the infection will require “track and trace” technologies to identify those who are at risk of infection.

For both these areas of scientific and technological response, there are health law aspects. These relate to fundamental human rights: the protection of participants in trials; access to medicines; protection in relation to medical devices; and privacy in relation to personal data. EU legislation is in place that already relates to these aspects, including the Charter of Fundamental Rights of the European Union (CFREU), the Clinical Trials Directive, the Medical Devices Directive and the General Data Protection Regulation.\(^{35}\)

**The Governance of Track and Trace-Technologies**

Privacy is a concern in relation to “track and trace”, as it requires individuals to divulge their locations to the State or to the commercial provider of the software used for the tracing. Each Member State is required to observe the European Convention on Human Rights, and the CFREU. Both these instruments create the right to private life, as a right in balance with the public interest, not as an absolute right.\(^{36}\) The General Data Protection Regulation reflects this. To process personal data fairly, lawfully and transparently, the Data Controller must have a legal basis for processing under Article 6 (general

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36 As stated above, rights under the Charter of Fundamental Rights of the European, in line with the Universal Declaration of Human Rights Article 12 and the European Convention on Human Rights Article 8, are not absolute: Article 52 allows the rights to be restricted to meet “the need to protect the rights and freedoms of others”.

personal data) and Article 9 (sensitive personal data - including health data). The legal bases for the processing are Article 6(1)(e) “processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller” and Article 9(2)(i) “processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy”.37

What is equally clear is that when there is an appeal to the public interest, the Data Controllers and Data Processors must still comply with the other elements of the GDPR, that the Data Subject should be informed of: the name and contact details of the Data Controller and the purpose of the processing;38 that the data must be kept securely, only for the stated purposes and not further processed for purposes incompatible with those purposes; and only data required for the processing must be gathered.39 The Data Controller, in devising the processing, must ensure compliance with the principle of “data protection by design and default” (that compliance with data protection is not an afterthought).40 Given the risks to individual privacy from “track and trace”, it must be in the range of processing subject to an impact assessment and be of a sufficiently high risk to warrant prior consultation with the national Supervisory Authority.41 The GDPR brought significantly increased fines for data breaches (over those available under Directive 95/46/EC).42 Where the processing of the personal data involves a transfer of the data, outside the EU, the processing institutions must comply with the GDPR.43

The European Data Protection Supervisor and European Data Protection Board must be at the forefront in setting standards that maintain public trust and confidence in the “track and trace” systems. The GDPR contains opportunities to

38 Articles 13 and 14, GDPR.
39 Article 5, GDPR.
40 Article 25, GDPR.
41 Articles 35 and 36, GDPR.
42 Article 83, GDPR.
43 Articles 44 to 50, GDPR.
process personal data in a way that both realises the necessity of “track and trace”, and is privacy-protecting. Writing at a time where a number of EU countries are moving towards whole population “track and trace” with global data science companies providing the software, and public concern about who will have access to sensitive data that reveals more than the Coronavirus status of the data subject, this will be a test for the GDPR, to see whether it is robust enough to provide both the confidentiality and the efficacy that the public demands.

**Clinical Trials and Medical Devices**

In terms of the development of the software application, clinical trials and the licensing of any new pharmaceutical products, the practical demand is for a regulatory system that protects citizens generally, and patients and research participants specifically. The EU has created key legislation (with procedures), as part of creating a single, harmonised research area, in relation to medical research, and single processes for licensing new pharmaceutical and medical devices, for sale in the EU. Each element has some problems. The European Medicines Agency overseas the licensing process for new pharmaceuticals to the EU. This is a well-established process but, like all regulators in this regard, it is faced with the challenge of what level of safety risk is acceptable for a product to respond to a pandemic that presents such devastating and immediate risks to the health of the population. This translates into the amount and quality of scientific data required to convince independent assessors of the safety and efficacy of the applicant drug. This is a challenge that has been addressed recently in relation to Ebola; the ethical issue continues in the current pandemic: who is a representative of the stakeholders in the debate and how are they heard in the debate?

In relation to medical devices, there is a question that has been emerging in recent years, not fully resolved at the practical or conceptual level: how far is a computer programme, or a wearable (or other) device, a medical device? As “track and trace” employs mobile phones and the GPS functions of smart watches, does this medical, public health function bring the whole device into the scope of EU medical devices law? This is compounded because the Medical Devices Regulation 2017/745 (MDR) was due to come into force in May 2020 but the European Parliament adopted the proposal, presented by the European Commission, postponing the entry into application of the MDR until May 26th 2021. Therefore the Directive 93/42/EEC remains in force.

A similar situation has occurred in relation to the EU legislation on Clinical Trials. The Clinical Trials Regulation 536/2014 should, by 2020, have been fully implemented. The process requires the development and implementation of the Clinical Trials Information System (CTIS) which includes a portal to facilitate the digital operation of the new trials approval system and a directory of trials. The creation of the CTIS has been extremely problematic and has delayed the implementation of the Regulation.\textsuperscript{45} The current legislation, for clinical trials approval, in the EU is the Directive 2001/20/EC. One of the main complaints about the Directive, and a motivation for the revision and development of the Regulation, is the time that it can take for the review of a protocol. Under the Directive, this could be a maximum of 60 days\textsuperscript{46}, with the possibility of extensions on the basis of inadequate information. A review could be expedited (and the European Network of Research Ethics Committees (EUREC) advocates that Research Ethics Committees (RECs) should prioritise Coronavirus and COVID-19 research applications, whilst observing all ethical standards). With the different infrastructures and arrangements for RECs across Europe, substantially reducing the time needed for a review could be difficult. The process created in the Directive, for multi-centre, multi-jurisdiction trials, does not have a mechanism for the coordination of REC assessments. Where a trial seeks to operate in multiple different jurisdictions, the applicants make multiple separate applications to the local RECs, and receive multiple separate evaluations that the applicant must reconcile. Expediting the process for emergency drugs is not clear. The ordinary process requires three phases for a clinical trial and usually a company will apply for a separate ethics review for each phase of the trial. How this process is expedited for emergency medicine situations is unclear.

\textbf{Economic Recovery}

One of the areas where there has been a lot of EU activity is in relation to maintaining the economies of the EU and its Member States.\textsuperscript{47} It is relevant

\textsuperscript{45} Regulation (EU) 536/2014 indicated that implementation would not be sooner than May 2016 (Article 99). Once the CTIS is in place, it requires an independent audit of the system, and the implementation of the Regulation will be six months after the completion of that audit. The current estimation by the EMA is that the audit will start in December 2020.

\textsuperscript{46} Article 6(5), Directive 2001/20/EC. For “trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms” the period can be extended to 90 days - Article 6(7).

\textsuperscript{47} For a broader discussion of the economic issues, see Remco van de Pas, (2020) Globalization Paradox and the Coronavirus Pandemic. Clingendael Report: Clingendael
because a strong economy is essential to realise the Charter Article 35 Right to Health Care and there are Treaty obligations on the EU to consider Health in All Policies.

The economic crisis, relating to COVID-19, follows countries’ strategies of “lockdown” - to require or advise individuals to isolate themselves, not to leave their homes unless it is essential, and to close many non-essential businesses and education institutions. In the EU, the responses of the Member States have been social lockdown to a greater or lesser extent, with consequent unemployment, collapse of many businesses, lost tax revenue and increased social-welfare spending demands.

The proposed EU response is to create a €750 billion fund of loans and grants. This money will be raised on the international markets, using the EU’s high credit rating to secure lower borrowing costs than might be available to some of its Member States individually. The draft budget proposals, for the next cycle of EU spending, had already reversed the previous policy regarding health and proposes a standalone health programme, with a view to raising health standards across the EU.

The experience of the response to the banking crisis of 2008 (the European Semester) was an embracing, by the EU, of austerity measures. This produced disproportionate impacts on the poorest members of society. If the response to the economic problems, caused by the COVID-19 pandemic, are met with the same policies (resisting and reducing public spending), then once again, this could have a longer-term impact on the health of the poorer European citizens. This is where the commitment to “Health in all Policies” and to the Charter’s Article 35 Right to Health Care will be tested.

Conclusions

This paper, has limitations. It is written only a few months into the COVID-19 pandemic in Europe, and more detailed evidence will emerge to make deeper judgements about the long-term contribution of the EU to the public and


economic health of its Member States and on the international stage. The purpose of the paper is: to explain the nature of the responses that have been seen in the EU health law context; to highlight where there are already issues in the current law or its operation; and to indicate where future effort is needed, both at the technical and conceptual level in relation to EU health law.

Whereas the EWRS worked in providing alerts about the nature of the threat, the EU does not have sufficient authority to coordinate the delivery of healthcare, at the point of use, between Member States. Practical healthcare support, between countries, has been largely bi-lateral.\(^{50}\) Whether this is the sort of response that realises the aims of the EU, or its commitment to fundamental human rights, should be debated (especially given the potential continuing duration of the pandemic). How far do the Member States (and their citizens) wish to move towards a federal EU? It is appropriate to link this debate to the response seen to the last crisis, faced by the EU, - the economic crisis of 2008 - where, as now, the instinct of the individual Member States was to sideline the EU and to assert their authority over the EU institutions. Will there be an economic response, based on austerity, and will any economic response be measured against its impact on individual citizens’ fundamental human rights, to access to health care and to share in the scientific and cultural (i.e. medical) advances of their community?\(^{51}\)

There are practical ways that the existing EU health law could be strengthened: the (spirit of the reforms in the) Clinical Trials Regulation and Medical Devices Regulation need to be implemented as soon as possible; the safeguards of the General Data Protection Regulation, particularly in relation to risk assessment and data protection, by design and default, must be ensured by robust scrutiny and enforcement by national and European supervisory authorities.

Beyond its own boundaries, the EU has taken a strong stance in contributing to the international effort in responding to the pandemic. The problem is one that is likely to remain for a number of years. One of the crucial elements, in responding to the continued crisis, is likely to be international co-operation,

\(^{50}\) This tension can also be observed with the procurement of prospective Covid-19 vaccines, whereby a coalition of four EU member states have concluded a joint EU vaccine strategy and budget coordinated by the European Commission. The concern raised is that four Member States have acted to bind all the Member States. [https://www.euractiv.com/section/all/short-news/belgium-criticises-vaccine-buying-solo-run/](https://www.euractiv.com/section/all/short-news/belgium-criticises-vaccine-buying-solo-run/) (last visited 16 June 2020).

\(^{51}\) See, Universal Declaration of Human Rights, Articles 25 and 27(1) (The United Nations, 1948, art. 21.3)
especially in the face of the United States of America’s withdrawal from the WHO. The EU’s continued voice, in international collaboration, is extremely important. The EU has a commitment to ensuring fundamental human rights. There is a temptation to see a pandemic as requiring a “state of exception” – an extraordinary response compared with the normal expectations, particularly in relation to human rights. Perhaps the greatest contribution that the EU could make is to: ensure that responses to the COVID-19 pandemic respect fundamental human rights to dignity and autonomy in the imperative context of solidarity; and that all jurisdictions recognise that one of the fundamentals of effective public health is maintaining human rights and the rule of law.

Appendix - A Brief Introduction to the EU and Health.

The European Union (EU) is a supranational organisation that has evolved into its current iteration as part of the twin projects to create a new Europe after its long history of wars culminating in World War II. The Council of Europe was created as an international, intergovernmental body to ensure European justice and culture; the EU is the current expression of the project to ensure peace through free trade, and to strengthen the combined position of its Member States in the context of the shifting geopolitical gravity.

After World War II, Belgium, France, West Germany, Italy, Luxembourg and The Netherlands first formed an alliance, around the production of coal and steel - the means of war. The broader project was to create a greater alliance. Churchill spoke of the need for a “United States of Europe”; Schumann created a plan to move to a united Europe. The twin growth trajectories of the degree of federation of the Member States, and the number of Member States have followed. From the 1950s, the number of Member States has moved from six, to nine, to 12, to 15, to 25, to 28, and, with Brexit, to 27. In terms of a geographical coverage, most of the countries in Western Europe are Member States of the EU and share public health risks through EU free movement policy.

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53 See Article 3(1) TEU
54 European Coal and Steel Community, Treaty of Paris, 1951.
The move from shared control over coal and steel to a European Economic Community was about creating a free trade area.\[^{56}\] The Maastricht Treaty, of 1992, took that trade community further towards a federal union - a “European Union” with the internal market, single currency and the social chapter. This proved a movement too far for many, with negotiated opt-outs from the social chapter and single currency from the outset. The derailment of the next phase of the trajectory followed with the rejection by Member States of the proposed “Constitution” of the EU.\[^{57}\] The purpose of the Lisbon Treaty (entering into force in 2009), in relation to the degree of federalisation, require two perspectives: it is merely a consolidation of the administrative changes necessary to run institutions with 27 Member States; it is the next step to federalism. From the early 1970s, this EU project has had, at its heart, the idea that Europe is one market where free movement of people to participate in that market is crucial. Where there is movement of people, animals, goods and services, across national (and internal) borders, there is a public health issue.

The TEU and TFEU create an explicit balance between the power of the EU and the power of the Member States.\[^{58}\] The EU has no exclusive power relating to health.\[^{59}\] The EU has shared power with the Member States to act in relation to “common safety concerns in public health matters, for the aspects defined in [the TFEU]”.\[^{60}\] Under specific conditions,\[^{61}\] the EU has a supplementary competence to: create legislation in order to meet common safety concerns in relation to health matters within specified, narrow areas relating to human blood and organs; to pharmaceutical and medical devices regulation; to phytosanitary issues in relation to health;\[^{62}\] it also has power to support Member States in relation to the promotion of health. It has a stated policy of “Health in All Policies and Activities” - that in everything it does, the institutions of

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\[^{59}\] Compare Article 3 TFEU.

\[^{60}\] Article 4(2)(k), TFEU.

\[^{61}\] See Articles 6 and 168 of the TFEU.

\[^{62}\] Article 168(4), TFEU.
the EU must consider the impacts on human health.\textsuperscript{63} The EU can also create legislation, binding on all its Member States, to “\textit{adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health}” but excluding any harmonisation of the laws and regulations of the individual Member States.\textsuperscript{64}

\footnotesize
\begin{itemize}
\item \textsuperscript{63} Article 168(1), TFEU.
\item \textsuperscript{64} Article 168(5) TFEU, which goes on to include specific power to create “measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.”
\end{itemize}
PERU
PERUVIAN EFFORT TO RESPONSE AND FIGHT COVID-19: HEALTH EMERGENCY

Rosa Teresa Meza Vásquez* y Giancarlo Jiménez Bazán**.

Abstract: Peru’s turn to confront the new virus called Covid-19 was inevitable. President Martín Vizcarra’s administration sought to contain the expansion of the virus just 5 days after the first case of an infected patient. These decisions were accompanied by unprecedented economic measures, which aimed to alleviate the impact the quarantined citizens of Peru. This effort failed to effectively reach the public promptly, despite their good intentions. The government’s strategy addressed three key issues detailed in this article. This is a country where a significant sector of the population is in poverty and extreme poverty, to whom the income strategy was not actively implemented using the transferred budget.

Keywords: Pandemic; Compulsory Social Isolation; Quarantine in Peru; Stay at Home

Introduction

At the Jorge Chavez International Airport, the arrival of passenger showing symptoms specified by the World Health Organization (WHO), especially those showing signs of coughing, difficulty breathing and, above all fever, was
expected. The idea was to confine this passenger arriving from Asia, specifically from China¹. Peru sought situational control by listing all contacts made by symptomatic people, prior to their arrival at the airport, to place them in isolation and avoid community spread. The Ministry of Health concentrated on preparing the transport² and place of isolation for these individuals and those with whom they came in contact at the airport³. However, the events did not occur as planned. Patient Zero did not arrive from Asia and did not present any symptoms: he went unnoticed through a process unprepared to contain him.

**Chronology and Actions Taken**

On March 6 2020⁴, the first COVID-19 patient, a 25 year old male, was confirmed – he had returned to Lima, Peru, from a trip in Europe⁵.

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¹ The “National Plan for the Preparation and Response to the Risk of Introduction of the Coronavirus 2019-nCov” was approved by Ministerial Resolution No 039-2020/MINSA, dated January 31st, 2020, which focused on people who had previously been in China and presented symptoms.

² The news about the measures and the Mobile Hospital enabled at the Jorge Chávez International Airport, located in the Constitutional Province of Callao, can be seen at: https://portaldeturismo.pe/noticia/minsa-muestra-hospital-movil-ante- posible-ingreso-de-coronavirus-por-aeropuerto-jorge-chavez/

³ The news that Peru had arrangements for the arrival of patient zero can be seen at: https://wwwelperuano.pe/noticia-plan-accion-frente-al-covid19-90634.aspx

⁴ The news can be consulted in https://andina.pe/agencia/noticia-presidente-vizcarra-confirma-primer-caso-coronavirus-peru-787293.aspx

⁵ Indeed, the patient zero arrived at Jorge Chavez International Airport in Lima, the capital of Peru, on February 26, 2020, he was asymptomatic and passed the controls easily, because in that time only those people with fever and who came from Asia mainly from China were sought. In an interview, the patient reported that on February 29, for the first time he had symptoms of cough without fever. When he went to a private hospital to rule out COVID-19, the COVID test was not carried out because he had no fever, so they sent him home, after this situation he called to National helpline number and a sample was taken. The first case of COVID-19 was confirmed on March 6, 2020. The patient infected his nuclear family: his grandfather and grandmother aged 78 and 74, respectively, as well as his 7-year-old cousin. The boy’s classes started on February 26, 2020. For that, the school was forced to suspended classes and closed. By that time, there were 6 COVID-19 positive people in Peru. The interview can be seen at https://www.facebook.com/ATVNoticias9/videos/766883033839827/?v=766883033839827 and the news of the student infected at https://gestion.pe/tendencias/coronavirus-en-peru-menor-de-siete-anos-es-uno-de-los-contagiados-nnde-noticia/ and https://rpp.pe/lima/actualidad/coronavirus-covid-19-colegio-newton-suspende-sus-clases-hasta-el-20-de-marzo-noticia-1250306
On March 11 2020, the World Health Organization (WHO) declared the COVID-19 a pandemic as its spread reached more than one hundred countries\(^6\). The same day, also in accordance with the WHO\(^7\), the Peruvian Government issued Supreme Decree No. 008-2020-SA to declare a National Health Emergency\(^8\) for a period of ninety (90) calendar days in response to COVID-19.

Thence, the Peruvian Government took progressive measures regarding the Coronavirus.

On 12 March 2020, by Vice-Ministerial Resolution No. 079-2020-MINEDU, the start of the new school year was suspended until 29 March. Technical schools, public and private institutes and universities were suspended until 30 March, by Vice-Ministerial Resolution No. 080-2020-MINEDU and Vice-Ministerial Resolution No. 081-2020-MINEDU respectively.

On March 13 2020, Supreme Decree No. 008-2020-MTC \(^10\) suspended the arrival/departure of flights from/to Europe and Asia.

The same day saw prohibition of any gathering with more than 300 people, in accordance with the Ministerial Resolution No. 297-2020-IN\(^11\), which mandated public adherence, as long as the Health Emergency remained in force.

Nine days after patient zero was confirmed, March 15, Peruvian President Engr. Martin Vizcarra broadcasted a televised message nationwide, calling a State of National Emergency\(^12\) and requiring all citizens to follow “Obligatory Social


\(^7\) According to Article 6(e) of Legislative Decree No. 1156 and Section 5.5 of Article 5 of Supreme Decree No. 007-2014-SA, the statement of pandemic by the World Health Organization constitutes a case of the health emergency.


\(^9\) The Health Emergency is defined by the Article 5 of Legislative Decree No. 1156: “The health emergency is a state of high risk or damage to the health and life of populations, resulting from the existence of situations of outbreaks, epidemics or pandemics. Likewise, a health emergency is when the response capacity of health system operators to reduce the high risk of the existence of an outbreak, epidemic or pandemic or to control it is insufficient at the local, regional or national level.”


\(^11\) This regulation can be seen at [https://busquedaselperuano.pe/normaslegales/suspenden-otorgamiento-de-garantias-inherentes-al-orden-publ-resolucion-ministerial-n-297-2020-in-1864485-1/](https://busquedaselperuano.pe/normaslegales/suspenden-otorgamiento-de-garantias-inherentes-al-orden-publ-resolucion-ministerial-n-297-2020-in-1864485-1/)

\(^12\) The State of Emergency is regulated in article 137 of the Political Constitution of Peru,
Isolation” for 15 days, starting on March 16\textsuperscript{13}, allowing only the activities the government deemed essential.\textsuperscript{14} The national borders were closed at 23:00 hours that day and all public, public-private and private hospitals were under the direction of the Ministry of Health during this Health Emergency period\textsuperscript{15}. The Peruvian President also ordered the armed forces\textsuperscript{16} to be on the streets to support the police forces, in ensuring compliance with all the provisions, as well as ordered all the health care institutions to contribute to the National Health System. These rules were officiated by Supreme Decree No. 044-2020-PCM\textsuperscript{17}.

Peru acted early in implementing quarantine, resulting in only 71 citizens infected with Covid-19\textsuperscript{18} and none yet registered deceased – the nation was described as

however, even in a state of emergency there are Human Rights that cannot be restricted, the foregoing in accordance with article 4 of the International Covenant on Civil and Political Rights and article 27 of the American Convention on Human Rights, ratified by Peru.

\textsuperscript{13} Under Articles 3 and 4 of Supreme Decree 044.2020-PCM, the exercise of Constitutional Rights concerning personal freedom and security, the inviolability of the home, and freedom for meeting and transit within the territory, included in Article 2, paragraphs 9, 11 and 12 and subparagraph f of paragraph 24 of the Political Constitution of Peru, was suspended. In addition, the exercise of the right of freedom of transit was limited, only being allowed for the purchase of food, medicines, and emergency health attention, and the development of activities considered essential.

\textsuperscript{14} According to article 2, in line with article 4 of Supreme Decree 044-2020-PCM, the following are considered essential goods and services: food supply, medicines, health services (health facilities and diagnostic centers for emergencies), water services, sanitation, electric power, gas, fuel, telecommunications, cleaning and solid waste collection, funeral services, financial institutions, insurance, pensions, and others.

\textsuperscript{15} However, the care of patients infected with Covid-19 free of charge is only carried out in public hospitals of the Ministry of Health and Regional Governments. Patients belonging to Social Security (workers) are cared for in the Social Security Hospital Network and patients who can pay directly or those who have private insurance are cared for in private hospitals. In this sense, the government has had to negotiate rates with private hospitals in order to send their patients to be treated in an Emergency when there were no beds available in the public hospital.

\textsuperscript{16} According to The Center of Latin American Studies of American University in Washington DC, Human Rights Groups expressed concerns about President Vizcarra has tapped the army to help enforce the quarantine but the militarization response rising Vizcarra’s popularity because the military also is helping to distribute supplies in poor areas and set up field hospitals. This information can be seen at Latin American responses to the Coronavirus: Some Inicial Hihtlights – Charles T. Call and Jeffrey Hallock https://www.american.edu/centers/latin-american-latino-studies/upload/clals-callhallock-piece-31march2020.pdf

\textsuperscript{17} This regulation can be seen at https://cdn.www.gob.pe/uploads/document/file/566448/DS044-PCM_1864948-2.pdf

\textsuperscript{18} The Peruvian Ministry of Health reported on Sunday, March 15, 2020, 71 people were
having the most restrictive quarantine in Latin America\textsuperscript{19}. The rate of infection in Peru, at that time, was 3, namely one infected person infected three others\textsuperscript{20}.

This nationwide mandatory social isolation was a great challenge for Peru, a country with an estimated population of 32,824,358 inhabitants\textsuperscript{21}. As of 2020, 20.5\% of Peruvian population is at, or below, the poverty line, equivalent to 6.5 million Peruvians, and 2.8\% are in extreme poverty\textsuperscript{22}.

Peru’s tough response was reasonable when considering the country’s health structure deficits. On March 6 2020, when the first case of infection was announced, there were only 100 Intensive Care Unit (ICU) beds available nationwide\textsuperscript{23} and on March 15 there were 276 ICU beds available – Peru was actively increasing its supply of ICU beds, to adapt to the spread of COVID-19.

This was aggravated by the fact that the number of physicians and nursing professionals was low\textsuperscript{24}; a Ministry of Health study, published in September 2019, reported that the number of medical doctors and nurses per 10,000 inhabitants was only 13.6 and 15.6\textsuperscript{25} respectively. This was worrying when compared to

\textsuperscript{19} This news can be seen at https://www.gob.pe/institucion/minsa/noticias/108935-comunicado-oficial-de-prensa-coronavirus-n-12

\textsuperscript{20} This information was given by the Peruvian President, Engr. Martin Vizcarra, at a press conference. The video can be seen at https://www.youtube.com/watch?v=bm-LOzlzNE4


\textsuperscript{22} On the basis of the provincial and district monetary poverty map published by the Peruvian National Institute of Statistics and Information. Lima, February 2020. P. 33 and subsequent. Monetary poverty is considered for people who survive on less than S/ 344 per month, which is equivalent to less than US$ 100; the report can be seen at https://www.inei.gob.pe/media/MenuRecursivo/publicaciones_digitales/Est/Lib1718/Libro.pdf

\textsuperscript{23} This information was given by the Peruvian President at a press conference. This video can be seen at https://canaln.pe/actualidad/martin-vizcarra-ahora-se-puede-atender-hasta-500-personas-que-lleguen-cuidados-intensivos-coronavirus-n410101.

\textsuperscript{24} The evolution of the number of health professionals mentioned above nationwide during the five years (2013-2018) is shown in Table No. 1. The information is from the Statistical Compendium of Human Resources Information in the Health Sector, Peru 2013-2018. General Directorate of Health Staff of the Ministry of Health. September 2019. P.30.

\textsuperscript{25} The number of medical doctors and nurses per 10,000 inhabitants between 2013 and 2018 is shown in Table No. 2. The information is from Statistical Compendium of Human Resources Information in the Health Sector, Peru 2013-2018 General Directorate of Health Staff of the Ministry of Health. September 2019. The Table 1 shows the evolution of the number of these professionals nationwide during this five-year period. P.22
the WHO’s\textsuperscript{26} estimates of a required minimum number of 23 of each for every 10,000 inhabitants to provide adequate health care coverage.

**Table N° 1**

<table>
<thead>
<tr>
<th>Region</th>
<th>2013</th>
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<td>24.5</td>
<td>15.5</td>
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<td>17.9</td>
<td>18.3</td>
<td>20.3</td>
<td>18.9</td>
<td>20.5</td>
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<td>5.2</td>
<td>5.1</td>
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**Table N° 2**

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<tr>
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<td>12.7</td>
<td>12.8</td>
<td>13.5</td>
<td>14.1</td>
<td>15.6</td>
</tr>
</tbody>
</table>

Source: Statistical Compendium of Human Resources Information in the Health Sector, Peru 2013-2018 General Directorate of Health Staff of the Ministry of Health. September 2019

\textsuperscript{26} The WHO recommendation can be seen at [https://www.who.int/hrh/workforce_mdgs/es/](https://www.who.int/hrh/workforce_mdgs/es/).
It was essential to reduce the level of contagion among the public to prevent the foreseeable overload and resulting collapse of the Peruvian health system through the compulsory confinement of the population.

Considering the difficulty of asking more than 6 million impoverished people to stay home, unable to make a daily income, the Peruvian government decided to implement economic support for the most vulnerable population. On March 17 2020, two days after the beginning of the quarantine, an amount of S/. 380\(^{27}\), approximately US$ 107\(^{28}\), was granted per person to cover the first fifteen days. According to the Peruvian Minister of Economy, Maria Antonieta Alva, the bonus was below the monthly minimum vital income of S/ 930 (US$ 262 approximately) as it was based on average urban food expenses without considering other expenses, such as rent\(^{29}\).

On March 18, the Government announced a curfew from 8 p.m. to 5 a.m. nationwide, except in the Loreto and Lambayeque Regions where it would begin at 6 p.m.\(^{30}\) Two towers were being dedicated exclusively to the care of Covid-19 patients in the village\(^{31}\), built to accommodate the athletes of the Pan American Games, held in Lima in 2019. These two towers provided 50 ICU beds and 150 hospitalization beds\(^{32}\), increasing the number of ICU beds to 236. The aim of the Ministry of Health was to gather the serious cases in this village to be attended to by highly specialized health staff.

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\(^{27}\) This news can be seen at https://elperuano.pe/noticia-gobierno-otorgara-un-bono-s-380-a-cada-familia-vulnerable-93123.aspx

\(^{28}\) Exchange rate S/ 3.545 per US dollar, published by the Peruvian Superintendence of Banking and Insurance (SBS) on March 17, 2020. This information can be seen at https://www.sbs.gob.pe/app/pp/SISTIP_PORTAL/Paginas/Publicacion/TipoCambioPromedio.aspx

\(^{29}\) This report can be seen at https://www.bbc.com/mundo/noticias-america-latina-51924224

\(^{30}\) This news can be seen at https://larepublica.pe/politica/2020/03/18/coronavirus-martin-vizcarra-sobre-toque-de-queda-esta-medida-es-para-evitar-la-prorroga-de-aislamiento/

\(^{31}\) The village built in the district of Villa El Salvador in Lima, capital of Peru, is a housing complex built to house 10,000 athletes in the Pan American Games in Lima 2019. The Village consists of 7 towers with 3,288 rooms, all equipped with water, power, natural gas, wide elevators, podo-tactile floors and Braille signs. The Peruvian government implemented two towers and the clubhouse for the care of COVID-19 infected people, the first phase finished on March 30, 2020 enabling 900 hospitalization beds. The attention is in charge of the Social Security-ESSALUD: https://www.lima2019.pe/noticias/villa-panamericana-legado-hoy-abre-puertas-para-recibir-pacientes-coronavirus

\(^{32}\) This news can be seen at https://www.gob.pe/institucion/minsa/noticias/109514-gobierno-presenta-nuevo-hospital-de-ate-que-sera-exclusivo-para-casos-de-coronavirus
That same day, the Ministry of Health announced a strategy to safeguard elderly people, a population at greater risk due to medical complications: they would be vaccinated at home against pneumococcus, with the process beginning in the city of Lima through teams focusing on nursing homes and shelters for the elderly. Pregnant women were advised to avoid health centers for prenatal check-ups, especially those with comorbidities such as hypertension, diabetes and malnutrition and recommended compliance with quarantine and only access emergency services if there is any sign of alarm, indicated on their prenatal control cards.

On March 19 2020, the Ministry of Health was briefed about the first death related to the disease, a 78-year-old man with a history of high blood pressure, admitted to the intensive care unit of the Peruvian Air Force Hospital, on March 17 due to severe respiratory failure. There were 234 infected people in Peru at that time, 19 hospitalized and 7 in Intensive Care Units.

On March 20, in the midst of the fight against Covid-19, the Minister of Health, M.D. Elizabeth Hinostroza, was replaced by M.D. Victor Zamora because he is a specialist in public health and the government considered him necessary in the face of the pandemic.

That same day, S/. 100,092,487 million soles, equivalent to slightly over US$ 28 million, was announced for a massive purchase of 1.6 million rapid and molecular test kits, as a strategic objective for the timely detection of infected people, and mandated any necessary isolation to avoid the chain of transmission. The aim was to carry out 12,000 tests a day.

33 The Official Statement No. 16 of the Peruvian Ministry of Health can be viewed in https://www.gob.pe/institucion/minsa/noticias/109459-pacientes-adultos-mayores-seran-vacunados-contra-el-neumococo-en-sus-domicilios-comunicado-n-16
34 This news can be seen at: https://www.gob.pe/institucion/minsa/noticias/109483-gestantes-deben-ir-a-emergencias-solo-si-presentan-signos-de-alarma-que-figuran-en-tarjetas-de-control-prenatal
35 The Official Statement No. 20 of the Ministry of Health can be seen at https://www.gob.pe/institucion/minsa/noticias/109580-minsa-lamenta-el-sensible-fallecimiento-del-primer-paciente-a-causa-de-infeccion-covid-19-comunicado-n-20
36 The number of infected can be consulted at https://www.gob.pe/institucion/minsa/noticias/109581-numero-de-nuevos-casos-de-covid-19-esta-dentro-de-la-curva-esperada-por-autoridades.
37 This news can be seen at https://elperuano.pe/noticia-victor-zamora-mesia-es-nuevo-ministro-salud-93289.aspx
38 This news can be seen at https://www.gob.pe/institucion/mef/noticias/109746-gobierno-
One day after being appointed, the new Minister of Health decided to suspend the vaccination for elderly people, until the end of quarantine, and vaccinated health professionals first. This decision was taken after the Dean of the Peruvian Nurses Association said that a nurse from the vaccination team had been infected and health workers were being sent out without adequate protection, requesting a vaccination plan for health care professionals\(^\text{39}\).

On March 26, 4 days before the compulsory 15-day quarantine ended, the Government announced a necessary extension until April 12, 2020, which was formalized by Supreme Decree No. 051-2020-PCM\(^\text{40}\).

On March 27 2020, the Peruvian government adopted other measures to reduce the quarantine’s economic impact, providing a second bonus of S/. 380, this time in favour of vulnerable households of 780,000 self-employed workers with no regular income. For dependent workers, they were allowed to freely dispose of their intangible funds from Service Time Compensation (CTS in Spanish) deposits, established by Law No. 30334, up to the amount of S/. 2,400, equivalent to US$ 677. For employers, the Government provided a 35% subsidy for the payroll of workers with salaries below S/ 1,500, equivalent to US$ 424. The Government provided an economic transfer of S/. 213,650,000, equivalent to US$ 60,267,938, to local governments, to assist in the purchase and distribution of family baskets of basic necessities. All these measures were formalized by Emergency Decree No. 033-2020\(^\text{41}\).

After the announcement of these measures, Peru was praised for the best economic plan in Latin America, mitigating the impact of the coronavirus crisis, reaching over US$ 25 billion, equivalent to 12.5% of the country’s Gross Domestic Product\(^\text{42}\). The Minister of Economy announced the plan would

\(^{39}\) This news can be seen at https://diariocorreo.pe/edicion/lima/confirmaron-que-enfermera-dio-positivo-por-covid-y-piden-se-suspenda-vacunacion-pandemia-contagios-noticia/

\(^{40}\) This regulation can be seen at https://busquedas.elperuano.pe/normaslegales/prorroga-del-estado-de-emergencia-nacional-declarado-mediante-decreto-supremo-no-051-2020-pcm-1865180-2/

\(^{41}\) This regulation can be seen at https://busquedas.elperuano.pe/normaslegales/decreto-de-urgencia-que-establece-medidas-para-reducir-el-im-decreto-de-urgencia-no-033-2020-1865180-1/

\(^{42}\) Also, the newspaper article states the great fiscal discipline sustained by Peru for three decades, allowed to undertake this Plan. This news can be seen at https://www.bbc.com/mundo/noticias-america-latina-52104166
consist on 3 phases with each having an estimated expense around US$ 8,500 million; the first would be a containment phase (by bonuses and subsidies), the second phase would consist of a loan scheme to companies guaranteed by the Peruvian State and the third an economic reactivation that would be done in 4 consecutive months.

On March 29, the Minister of Health stated that most of the infected were registered in Metropolitan Lima and the Loreto region in the Amazon jungle, where they had also been facing dengue fever43.

On March 30, the President strengthened the curfew by starting it at 6 pm, instead of 8 pm to 5 am, to address the ongoing non-compliance. The curfew in the 5 regions of Piura, Tumbes, La Libertad, Lambayeque, and Loreto would start at 4 pm44.

1,065 positive cases were announced at the end of March: 190 hospitalized, 57 in ICU beds and 30 deaths45.

On April 1st, the Government announced the creation of the Covid Command, composed of specialists with outstanding careers from all areas of the health sector, to implement all actions aimed at the care of infected patients46.

The Chief of the Peruvian Covid Command, two days after beginning work, stated the list of assisted ventilation equipment in health facilities in the whole public and private health sector had been unified. The number of equipment available had increased from 276 to 500. The Peruvian President, at a press conference, informed about the manufacture of ventilators in the country that had begun through the specialized personnel of the Peruvian Navy – 10 units in the next few days were expected, known as “Samay”48.

43 This article can be seen at https://www.gob.pe/institucion/minsa/noticias/111596-ministro-zamora-en-loreto-se-necesita-reforzar-la-vigilancia-epidemiologica
44 This news can be seen at https://exitosanoticas.pe/v1/toque-de-queda-desde-las-6-pm-y-en-5-regiones-empieza-a-las-4-pm/
45 This report can be seen at https://www.gob.pe/institucion/minsa/noticias/111623-minsa-casos-confirmados-por-coronavirus-covid-19-asciende-a-950-en-el-peru-comunicado-n-41
46 This news can be seen at: https://elperuano.pe/noticia-creacion-comando-covid-potenciara-labor-sanitaria-93799.aspx
47 The availability of ICU in Peru has risen to 500 https://www.gob.pe/institucion/minsa/noticias/111799-comando-de-operaciones-covid-19-eleva-a-500-la-disponibilidad-de-ventiladores-mecanicos-para-enfrentar-la-pandemia
48 The word “Samay” comes from the Quechua language, which is an Andes Peruvian native
On April 3, the Peruvian State launched the web page known as Situational Data Covid-19 ("Sala Situacional Covid-19" in Spanish) to share relevant information online, where all updated statistical information can be consulted.

By April 7, a total of 330,000 rapid tests had arrived in Peru which were being applied complementarily to the molecular tests: 10,104 rapid tests had been applied, of which 9,572 were negative and 532 were positive.

On April 8, the Peruvian President announced that the quarantine shall be extended to April 26, 2020 and the number of infected people was 4,342.

By April 9, 9,000 daily tests were being performed, totalling to 56,681 tests completed with 5,897 positive results. On April 14, 10,000 daily tests were carried out, the highest number of daily sampling in South America, and totalled to the processing of 102,216 samples with molecular and serological or rapid tests, with 10,303 positive results.

Also on April 9, Peruvian Ombudsman Atty. Walter Gutierrez said only 10 regions of Peru had implemented the 10% of the budget granted by the Economy and Finance Ministry to deal with the pandemic. Among those Government Regions that had not executed their budget were the most affected by the virus: Callao, Piura y Lambayeque, which had only executed 7.3%, 2.5%, and 1.7% of it, respectively. The government decided to implement the Lambayeque region’s budget.

language it means “breathe”, the news can be seen at https://www.gob.pe/institucion/minsa/noticias/111871-peru-producira-sus-propios-respiradores-artificiales-para-la-atencion-de-pacientes-covid-19

49 The Situational Data of Covid-19 in Peru can be seen at https://covid19.minsa.gob.pe/sala_situacional.asp

50 news can be seen at https://www.gob.pe/institucion/minsa/noticias/112060-son-330-millas-pruebas-rapidas-distribuidas-en-lima-y-regiones

51 This news can be seen at https://andina.pe/agencia/noticia-cuarentena-coronavirus-se-amplia-hasta-26-abril-anuncia-presidente-vizcarra-792152.aspx

52 This news can be seen at https://www.gob.pe/institucion/minsa/noticias/112153-peru-analiza-9-000-pruebas-dias-como-parte-de-estrategia-para-combatir-el-covid-19

53 This news can be seen at https://www.gob.pe/institucion/minsa/noticias/119197-minsa-supero-las-10-mil-pruebas-dias-para-vigilar-el-comportamiento-del-covid-19-en-el-pais

54 The news report states that when they consulting the Economy and Finance Ministry’s website 15 regional governments had implemented less than 10% of the budget granted. This news report is available in https://ojo-publico.com/1740/dato-de-defensor-del-pueblo-de-gasto-para-combatir-covid-19-es-cierto

55 The newspaper report states that the Lambayeque region was granted S/. 15,808,843 for the national emergency and has implemented 24.4% as of April 30. On April 30,
On April 14, 2020, the government published the Ministerial Resolution No. 193-2020-MINSA, a technical document for the prevention, diagnosis and treatment for people affected by Covid-19 in Peru. This document indicated the different medicines that must be applied for the treatment of patients with mild, moderate and severe cases. The treatments involve Chloroquine Phosphate, Hydroxychloroquine and Azithromycin, avoiding the use of non-steroidal anti-inflammatory drugs.

On April 19, the second rapid test batch arrived, consisting of another 330,000 kits from China, allowing 12,000 tests per day. The Minister of Health said that these tests were prioritized for frontline health care personnel as well as the police and military. On that day, 15,628 confirmed positive cases were reported.

The same day, Emergency Decree No. 042-2020 was enacted to grant a bonus of S/. 760 soles, equivalent to US $ 214, in favour of households in poverty or extreme poverty in the rural area, amounting to a total of S/. 836,180,640.

Continuing with its economic Plan, on April 23, the Government announced an additional Universal Family Bonus of S/. 760 to address the 6.8 million households (75% of the nation) that do not have regular income and are not on the payroll as dependent workers, mobilizing a total of 5.168 million soles.

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the Ombudsman’s Office asked the Prosecutor’s Office to investigate the “negligible” budgetary expenditure for handling the Covid-19 cases in Lambayeque. Also, the chief of the Ombudsman’s Office of Lambayeque, Julio Hidalgo, indicated that S/.15,808,843 is not being implemented effectively, efficiently and diligently and despite “46 days have passed (April 30), and having the Lambayeque Region a larger care needs in the health services to attend to the Covid-19 cases, the budgetary progress is really very small.” The information can be seen at [https://www.laindustriadechiclayo.pe/noticia/1588482063-gobierno-central-ejecutara-el-presupuesto-de-lambayeque-destinado-a-enfrentar-el-covid-19](https://www.laindustriadechiclayo.pe/noticia/1588482063-gobierno-central-ejecutara-el-presupuesto-de-lambayeque-destinado-a-enfrentar-el-covid-19)

This news can be seen at [https://www.tvperu.gob.pe/noticias/nacionales/covid-19-llega-al-pais-segundo-lote-de-300-mil-pruebas-rapidas](https://www.tvperu.gob.pe/noticias/nacionales/covid-19-llega-al-pais-segundo-lote-de-300-mil-pruebas-rapidas)


This regulation can be seen at [https://busquedas.elperuano.pe/normaslegales/decreto-de-urgencia-que-establece-medidas-extraordinarias-de-decreto-de-urgencia-n-042-2020-1865631-2/](https://busquedas.elperuano.pe/normaslegales/decreto-de-urgencia-que-establece-medidas-extraordinarias-de-decreto-de-urgencia-n-042-2020-1865631-2/)

This news can be seen at [https://rpp.pe/economia/economia/gobierno-extendera-bono-de-s-760-quienes-seran-los-beneficiados-noticia-1260638](https://rpp.pe/economia/economia/gobierno-extendera-bono-de-s-760-quienes-seran-los-beneficiados-noticia-1260638)
The Ombudsman’s office stated that the distribution channels of bonuses towards impoverished families must be prompt improved for timely payment\(^{60}\).

On April 24 2020, two more towers of the Pan American Village were made available, increasing the nation’s capacity by 1,000 additional beds for patients with Covid-19 who required hospitalization without intensive care\(^{61}\). At that time, the number of confirmed cases was 27,517\(^{62}\).

Five days later, the Ministry of Health informed that the Unified Health System had 822 ICU beds and 637 of these were in use leaving 185 available nationwide\(^{63}\). 517 of ICU beds were in Lima and Callao, with 488 in use and only 29 available.

On May 6, the Dean of the Peruvian Nurses Association indicated 1,278 infected nurses nationwide, consequent to the lack of personal protection equipment\(^{64}\). Also, the Peruvian Medical Association reported the death of four physicians and one other who had his bachelor’s degree in medicine\(^{65}\). This day saw 1,600 beds in the Pan American Village occupied, becoming one of the largest isolation complexes on the continent\(^{66}\).

On May 8, 2020, the 54\(^{th}\) day of the State of Emergency, the Peruvian President, Engr. Martin Vizcarra, declared that the quarantine shall extend for two more weeks, namely until May 24 2020\(^{67}\), as the infection rate was at 1.2, still too high for the goal of 1. The number of people infected by Covid-19 was 61,847.

\(^{60}\) The Ombudsman Office recommendation on April 7, 2020, was made long before the announcement. This information can be seen at: https://www.defensoria.gob.pe/defensoria-del-pueblo-se-debe-fortalecer-los-canales-de-atencion-para-cobro-oportuno-del-bono-de-s-380-por-parte-de-familias-pobres/

\(^{61}\) Also, a tower was equipped for a health staff housing that works in the Village: the news can be seen at https://www.lima2019.pe/noticias/villa-panamericana-aumento-capacidad-para-atender-pacientes-coronavirus

\(^{62}\) This news can be seen at https://www.gob.pe/institucion/minsa/noticias/131667-minsa-casos-confirmados-por-coronavirus-covid-19-ascienden-a-27-517-en-el-peru-comunicado-n-78

\(^{63}\) This announcement can be seen at https://www.gob.pe/institucion/minsa/noticias/142142-peru-implemento-822-camas-uci-para-la-atencion-de-pacientes-covid-19

\(^{64}\) This news can be seen at https://gestion.pe/peru/coronavirus-peru-colegio-de-enfermeros-del-peru-pide-que-se-amplie-el-estado-de-emergencia-hasta-fines-de-mayo-estado-de-emergencia-cuarentena-nndc-noticia/

\(^{65}\) This statement can be seen at https://www.cmp.org.pe/cmp-realiza-izamiento-a-medi-asta-en-honor-a-medicos-fallecidos/

\(^{66}\) This news can be seen at https://www.lima2019.pe/noticias/legado-juegos-panamericanos-lima-2019-emergencia-sanitaria

\(^{67}\) The press conference can be seen at https://www.youtube.com/watch?v=bm-LOzIzNE4
The same day, Ministerial Resolution No. 270-2020-MINSA was published and indicated the cardiovascular adverse effects of Chloroquine and Hydroxychloroquine, recommending that an initial electrocardiogram be performed and repeated every 3rd day from the beginning of the patient’s treatment with these drugs.

The government’s focus on Covid-19 patients inevitably reduced attention regarding those non-infected who had chronic and/or severe illnesses, with or without being immunocompromised. The non-infected patients experienced interruptions with many of their ongoing treatment, diminished quality of life, deterioration of their health and illness, aggravation with the latency of developing severe complications.

In the midst of this tragedy for the patients mentioned above, by Ministerial Resolution No. 262-2020-MINSA, a Technical Document on the Treatment of Oncological Patients during the Covid-19 Pandemic, was published to address the need to initiate or continue such treatment (especially chemotherapy, oncological surgery or radiotherapy). Patients’ needs for treatment were assessed through individual evaluations, based on different considerations, such as clinical stage, age, type of cancer and prognosis, while also informing them on the increased risks of contagion from Covid-19. For other kinds of chronic illnesses, there was no pronouncement or possibility for patients to start or continue their treatment at hospital or to receive their medicine.

Since May 10 2020, by Legislative Decree No. 1490, the government tried to promote direct telemedicine, for the first time in Peru, for medical consultations that were suspended nationwide, since the start of the Health Emergency. This practice nullified any risk of contagion, between physician and patient, especially for those most vulnerable to Covid-19.

Not all hospitals, in the health system, have the necessary platforms or tools to carry out teleconsultation or were not enrolled in the national telemedicine network. Patients were not accustomed to this new method of consultation as, for the past 15 years such teleconsultation were only carried out by a health

68 The regulation was published on 12 May 2020 https://www.gob.pe/institucion/minsa/normas-legales/563114-262-2020-minsa
professional from health establishments in remote or rural areas, to gain access to a specialist physician from more complex hospitals, where the patient may or may not be present\(^70\).

Elective surgeries were also suspended to enable resources to address the pandemic and only emergency surgeries were performed.

At the time of writing this article, Peru did not have the statistics regarding the total numbers of elective surgeries that were suspended in the country. According to research, by University of Birmingham\(^71\), an estimated 7,478 elective surgeries were cancelled each week in Peru, due to Covid-19.

On May 12, the Dean of the Peruvian Medical Association reported 820 physicians were infected with 16 deceased\(^72\), 11 of whom were from the Loreto Region\(^73\) which had a ratio of 7.2 physicians for every 10,000 inhabitants in a population of 1,085,375\(^74,75\).

Conclusions

In Peru, it has been necessary to provide Personal Protection Equipment, medicines, oxygen balloons, increase the numbers of hospitalization and ICU beds and hire more healthcare professionals. The overcrowding of deaths in

\(^70\) The Peruvian National Telemedicine Network has 2,043 integrated health centers. Up to December 31, 2019 these health centers carried out only 6,170 teleconsultations nationwide.


\(^72\) This news can be seen at https://gestion.pe/peru/collegio-medico-del-peru-820-galenos-estan-contagiados-de-covid-19-y-16-han-fallecidos-mndc-noticia/

\(^73\) According to the Environmental Analysis of the Loreto Region published by the Environmental Committee of the Loreto Region, in October 2010, the aforementioned region, located in the Peruvian Amazon Jungle, represents the 28.7% of the Peruvian territory and has 7 provinces: Maynas (capital Iquitos), Alto Amazonas (Yurimaguas), Loreto (Nauta), Requena (Requena), Ramon Castilla (Caballo Cocha), Ucayali (Contamana) and Datem del Marañon (Barranca), consisting on 51 districts.


\(^75\) Statistical Compendium of Human Resources Information in the Health Sector, Peru 2013-2018 General Directorate of Health Staff of the Ministry of Health. September 2019. The density of medical doctors per 10,000 inhabitants in the indicated five-year period at Loreto Region and the other three regions having the highest number of infections in Peru.
represents a potential source of infection especially in the highest number of Covid-19 infections in five regions in Peru: Lima, Callao, Lambayeque, Piura, and Loreto.\textsuperscript{76} may describe the limited resources available, especially true for the last 3 regions mentioned that showed much higher rates of death than the national average.\textsuperscript{77}

As of May 13 2020, a total of 73,306 diagnosed cases have been detected in Peru, with 2,169 deaths, 6,979 patients hospitalized and 806 under mechanical ventilation.\textsuperscript{78} Although Peru responded promptly, it is facing the reality of poverty, which forced people to ignore and to break quarantine restrictions to work and provide for basic necessities, despite risks of contagion. With the first economic bonds failing to reach all their beneficiaries, and the implementation of other bonds delayed, the financial bonuses were only appropriately distributed since May 14, 71 days from the start of social isolation.

The poor hospital infrastructure is evidenced by the excessively low availability of ICU and hospitalization beds nationwide, the overcrowding of hospitals, especially in Loreto, Piura and Lambayeque regions where there are not enough beds for all patients, the lack of oxygen provision, mechanical ventilation and drugs needed and the health professionals’ inadequate access to personal protection equipment. The most populated city, in the Loreto region, saw 12 physician deaths, 192 infected, 46 hospitalized patients (21 were transported to Lima and 25 remain in Iquitos) and 13 in the ICU (8 in Lima and 5 in Iquitos).\textsuperscript{79} 15 infected nurses were reported at the Regional Hospital of Loreto, 13 in hospital, 5 of them receiving oxygen treatment and 3 in the ICU. Regarding nursing technicians, 2 infected at the Hospitalization Service with 1 of them receiving oxygen treatment.\textsuperscript{80}

\textsuperscript{76} This news can be seen at https://www.france24.com/es/20200513-m%C3%A9dicos-peruanos-protestan-por-falta-de-equipos-de-seguridad
\textsuperscript{77} According to the publication on May 13, 2020, in the Peruvian Situational Data, Peru’s fatality rate is 2.84%, regarding that Piura Region has a much higher fatality rate of 10.92%, Lambayeque 10.56%, and Loreto 4.52%. The information can be seen at https://covid19.minsa.gob.pe/sala_situacional.asp
\textsuperscript{78} Minister of Health, until May 13, 2020.
\textsuperscript{79} This information was published by M.D. Max Theme Florez, Former Loreto Regional Dean of the Peruvian Medical Association and current Medical Care Physician of the Regional Hospital of Loreto regarding information updated to May 13, 2020.
\textsuperscript{80} information was provided by M.D. Graciela Meza Sanchez, Former Loreto Regional Dean of the Peruvian Medical Association and current Medical Care Physician of the Regional Hospital of Loreto regarding information updated to May 13, 2020.
At the time of writing this article, according to the quarantine extension, formalized by Supreme Decree No. 094-2020-PCM on May 23, 2020, the quarantine in Peru was extended until June 30 2020\(^8\), three and a half months of continuous obligatory social isolation. On May 24 2020, the number of infected people was 119,959\(^8\).

Although the number of infections across the country is constantly increasing, the government indicates that the infection rate has decreased. However, if the strategy of the Peruvian Ministry of Health is to carry out the largest number of rapid tests daily (34,799 tests from May 24 to May 25, 2020) it must be followed-up with medical assistance and treatment for Covid-19 patients. At the same time it is necessary to establish a regional approach of management for this pandemic, suggested by analysts to address the varying needs in appropriate ways.

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81 This regulation can be seen at https://busquedaselperuano.pe/normaslegales/decreto-supremo-que-establece-las-medidas-que-debe-observar-decreto-supremo-n-094-2020-pcm-1866708-1/

82 This report can be seen at https://covid19.minsa.gob.pe/sala_situacional.asp
RUSSIA
COVID-19 IN RUSSIA: NOVELS OF LEGAL REGULATION OF HEALTHCARE

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Abstract: The article describes the timeline of the spread of COVID-19 in Russia, examines the legal nature of the high alert regime and restrictions and the grounds for their phased withdrawal. Newly defined administrative and criminal liabilities, in the context of epidemic, are introduced. A set of measures is considered to overcome the healthcare system’s organizational crisis during the pandemic: changing the rules for providing medical care; the mechanism of work of medical organizations; and introducing state support measures, including for medical experts working with patients with COVID-19.

The patient’s legal status during a pandemic is investigated: general innovations of a supportive nature; restrictive measures for patients with COVID-19; and the situation of people with other serious illnesses. Introduction of power measures without defined legal parameters risks the balance of rights.

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Introduction

On January 30 2020, at a meeting of the World Health Organization’s (WHO) emergency committee, the outbreak of the new coronavirus was recognized as a public health emergency of international concern. On March 11 2020, the WHO officially recognized it as a pandemic.

In Russia, the first case of COVID -19 infection was recorded on January 31 2020.1 The virus’s source seemed to be beyond Russian borders: it was detected in the Trans-Baikal Territory and the Tyumen Region of two arrived Chinese citizens. The main increase in the number of detected cases began in mid-March, due to timely preventive measures taken by executive authorities.


The restrictions were introduced in Russia for the first time in history. The measures to prevent the increase in COVID infections were as follows: self-isolation; communication with foreign countries; classified non-working days; introduction of the regime limits measures; widespread thermometry of the population; establishment of adaptive patient-medication systems; and state control of pricing of medical devices, which is a significant element in protecting against potential infection. New measures of administrative and criminal liability for violation of restrictions were introduced.

The spread of COVID -19 in Russia, at the beginning of the pandemic, did not exceed the European average and amounted to ~20% and, after the introduction of more stringent restrictive measures, including self-isolation, it fell to 3%. Less than 2 months after the introduction of the self-isolation, the distribution coefficient of coronavirus in Russia decreased to 0.89 and to 0.72 in Moscow.2

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2 https://tass.ru/obschestvo/8506237.
According to the Ministry of Health of Russia, more than 40% of citizens testing positive for coronavirus did not have any clinical manifestations. Though in 3rd place, in terms of detected cases, the number of deaths, as of May 24th 2020, amounted to 3249 people – less than 1% of the detected cases.

In Russia, as of May 24th 2020, according to WHO and The Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, more than 8 million tests for Coronavirus were completed - the second largest count internationally. To obtain data, on the emerging collective immunity in Moscow, free testing for antibodies to COVID-19 began on May 15th 2020. The data accumulated by May 22nd indicated that among the 40 thousand tested, 14% were positive for the antibodies.

The Minister of Health of the Russian Federation believes that the first vaccines against coronavirus will appear in late July, with a statement supported by Russia’s chief sanitary doctor stated that vaccination against coronavirus will begin with at-risk groups.

The article discusses and systematizes the novels of Russian legislation on:

• restrictions and prohibitions introduced in the territory, as well as liability for failure to comply
• measures aimed at organizing the provision of medical care during a pandemic
• the legal status of patients, particularly the general innovations of a supportive nature; restrictive measures for patients with COVID-19 and the legal status of persons with other serious illnesses.

1. Restrictions in the Context of the Epidemic Spread of COVID-19 and the Liabilities for their Violation

1.1 Legal Basis for the Introduction of High Alert Status and Removal of Restrictions and Prohibitions

High alert was introduced in the constituent entities of the Russian Federation, based on the provisions of Article 72 of the Constitution of the Russian Federation⁹ which established joint jurisdiction of the Russian Federation and its constituent entities in relation to the implementation of measures to combat disasters, natural disasters, epidemics and the elimination of their consequences on the basis of Federal Laws¹⁰.

The Decree of the President of the Russian Federation, on April 2, 2020, No. 239¹¹ and continued acts of the federal government¹²,¹³ propelled highest officials of said entities to develop a set of restrictive measures to counteract the spread of COVID-19. This national effort was based on the sanitary and epidemiological situations in each entity.

The activities of organizations and individual entrepreneurs were suspended and limited and a special procedure for movement was established to involve the methodological recommendations of consumer protection agency, Rospotrebnadzor¹⁴ and chief state doctors. These measures did not apply to medical and pharmacy organizations, grocery organizations and others providing emergency and essential services¹⁵.

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¹¹ Decree of the President of the Russian Federation of 02.04.2020 N 239 “On measures to ensure the sanitary and epidemiological well-being of the population in the Russian Federation in connection with the spread of a new coronavirus infection (COVID-19)”.
¹⁵ Decree of the President of the Russian Federation of 02.04.2020 N 239 “On measures to ensure the sanitary and epidemiological well-being of the population in the Russian Federation in connection with the spread of a new coronavirus infection (COVID-19)”.
The effectiveness of these restrictions will be evaluated at the end of the pandemic. This is a topic for our further comparative study of different nations’ situations.

Rospotrebnadzor proposed\(^\text{16}\) the \textbf{phased removal of restrictive measures} which will involve 3 stages. The decision on specific measures at each stage is assigned to the head of the region at the suggestion of the chief sanitary doctors and in case of complications of the epidemic, restrictive measures may be resumed.

Some rules are expected to be maintained, until the creation of a vaccine against COVID-19. To adapt to life with the virus, special guidelines have been developed for various industries.\(^\text{17}\)

Restrictive measures differ in the territories of constituent entities depending on the degree of infection within that region.

\section*{1.2 Restrictive Measures on the Example of Moscow}

On May 24, 2020, the recorded cases totaled 326,448 with 163,913\(^\text{18}\) in Moscow - more than 50% of all identified cases. After May 25, less than half of the cases in Russia were recorded in Moscow and the number of people who recovered exceeded the number of those infected.\(^\text{19}\)

In Moscow, where COVID-19 had the highest spread, the most restrictive measures were introduced.

By a decree of the Mayor of Moscow, dated as early as March 5, 2020\(^\text{20}\), a high-alert mode was introduced due to the threat of the spread of COVID-19. Complementing federal bans, it included a ban on all public events, religious facilities (until June 14, 2020), suspension of visiting city cemeteries, except if participating in a burial. It suspended: restaurant operations excepting take-away and delivery services; provision of short-term car rental services (car-sharing

\begin{itemize}
\item \textit{“MR 3.1.0178-20. 3.1. Prevention of infectious diseases. Methodological recommendations. Determination of a set of measures, as well as indicators that are the basis for the phased removal of restrictive measures in the context of the epidemic spread of COVID-19” (approved by the Chief State Sanitary Doctor of the Russian Federation 05/08/2020).}
\item \textit{tass.ru/obschestvo/8429201.}
\item \textit{Operational Headquarters for Combating coronavirus in Russia, https://t.me/COVID2019_official.}
\item \textit{Ibid.}
\item \textit{Decree of the Mayor of Moscow dated March 5, 2020, No. 12-UM “On the introduction of a high alert mode” with subsequent amendments.}
\end{itemize}
services); and passenger transportation services on request, with the exception of taxi services. Operating facilities were also mandated to implement personal respiratory (masks, respirators) and hands (gloves) sanitation and protection.

From March 21st, students were suspended from visiting educational organizations, with rapid spread to include all student facilities throughout the country.

City authorities required people to use personal protective equipment for respiration (masks, respirators) and hands (gloves) when on public transport and visiting locations of trade. It became obligatory to maintain a distance of at least 1.5 meters (social distance) between individuals in public places and public transport. Visiting the nearest food store or pharmacy, walking pets, taking out garbage - at a distance not exceeding 100 meters from the place of residence, applying for emergency medical care, going to work were the only exceptions to self-isolation.

**Moscow authorities obliged visitors of “COVID-19 countries” to** inform about return the Russian Federation, regarding: place(s) visited; dates of stay in these areas; contact information on the hotline of Moscow; and self-isolate at home for 14 days from the day of returning together with cohabiting ones.

**COVID-19 infected and**\(^{21}\) **suspected individuals, as well as people with symptoms of acute respiratory diseases and co-habitants** to enable monitoring of compliance with self-isolation (isolation) at home, were required to use electronic technology monitoring their locations. These individuals were only allowed to mobilize when requiring necessary medical care.

**As the number of cases increased, digital skipping mode was introduced to keep as many people as possible at home.**\(^{22}\) An electronic pass, was issued on the website or via SMS, for 1 calendar day, but no more than 2 times a week, for any purpose, and without restriction, in case of movement to receive medical care. For those who continued to work, a pass was issued without any limitations.

The measures, taken by the Russian authorities, turned out to be timely and effective, although some experts noted that the restrictions could have been

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\(^{21}\) Effective from April 22, 2020.

\(^{22}\) Decree of the Mayor of Moscow of April 11, 2020, N 43-UM “On approval of the Procedure for processing and using digital passes for moving around the territory of the city of Moscow during the period of high availability in Moscow”.
introduced earlier. Despite the decisions, which were prepared by the state authorities in advance, not all of them were implemented at an earlier date due to citizens’ negative attitudes towards these restrictive measures. Only later did society endorse severe restrictions. State power found itself in a difficult situation, the precedents of which had not existed in modern history. Introduction of tough measures was justified for reducing the spread of the epidemic while protests could be provoked by early severe restrictions and lower the level of approval of government decisions resulting in a refusal to follow such mandates.

It is necessary to clearly define the legal mechanism for the introduction and implementation of appropriate preparation for this pandemic, considering the constitutional division of powers between federal and regional government bodies, as per the Constitution of the Russian Federation (part 3 of article 55), to restrict constitutional human rights and freedoms only through the adoption of federal law.

1.3 COVID-19 Novels of Administrative and Criminal Liability

The media continued disseminating information about non-compliance, indicating a lack of motivation for people to ensure the safety of life and health of both for themselves and those around them. Failure to comply with sanitary and epidemiological rules inevitably would lead to defeat in the fight against the spread of COVID-19.

On April 1st 2020, the deputies of the State Duma of the Russian Federation and the Government of the Russian Federation developed and entered into force two new federal laws that strengthened administrative and criminal liability for violations of sanitary and epidemiological rules, including violation of quarantine, and self-isolation, and introducing liability for the distribution of fake information, as described below, related to the coronavirus epidemic.

23 rg.ru/2020/03/24/strogij-karantin-podderzhali-bolshinstvo-rossiian.html.
24 Pospelov S.V. Abstracts of the MGIMO (U) International Online Conference “Pandemic as a Transformation Engine”.
The new laws aimed at improving mechanisms to protect health of citizens from the spread of disease (including coronavirus infections) and to increase the social responsibility of those infected, potential carriers and uninfected individuals.

Unlike criminal liability, administrative liability can be established both at the federal level and that of the subject of the Russian Federation. The regions are not entitled to impose fines in the amount higher than those imposed in the federal code.

The authorities of some constituent entities of the Russian Federation imposed fines for failure to comply with the rules of conduct associated with high alert statuses. In such entities, regional fines applied and, in the entities in which penalties for violation of said rules of conduct, were not imposed, federal standards applied. In Moscow, a fine of 4,000 rubles\(^\text{28}\) was imposed for violating the self-isolation regime (if the offender was driving a car - 5,000 rubles) and at the federal level - from 1,000 to 30,000 rubles.\(^\text{29}\)

**Violation of the Legislation in the Field of Ensuring the Sanitary and Epidemiological Welfare of the Population**

1/ Administrative Responsibility

Until April 1\(^\text{st}\) 2020, Article 6.3 of the Administrative Code of the Russian Federation (hereinafter – AC RF) provided for administrative liability only for violation of legislation regarding sanitary and epidemiological welfare of the population, defined as both violation of and failure to comply with sanitary, hygienic and anti-epidemic measures (maximum fine for individuals — 500 rubles).

From April 1\(^\text{st}\)\(^\text{30}\), this article was supplemented by 2 new parts\(^\text{31}\). According to one of them, administrative responsibility entails the commission of the same act during the emergency situation regime or when there is a threat of the spread of a disease that poses a danger to others, or during the quarantine.

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29 Law of Moscow dated 01.04.2020, No. 6 “On Amendments to Articles 2 and 8 of the Law of the City of Moscow dated December 10, 2003 No. 77 On Public Law Enforcement Points in Moscow” and the Law of the City of Moscow dated November 21, 2007, No. 45 “Moscow City Code of Administrative Offenses”.
30 Federal Law of April 1, 2020, N 99-FL.
31 Parts 2 and 3 of Article 6.3 of the AC RF.
Penalties set for those violating quarantine were much higher: for individuals a fine of 15,000-40,000 rubles, for officials 50,000-150,000 rubles and for legal entities 200,000-500,000 rubles or suspension of activity for up to 90 days.

If such violation resulted in harm to human health or death of one person, the punishment would be more severe: a fine of 150,000-300,000 rubles for individuals, for officials 300,000-500,000 rubles or disqualification for a period of 1 to 3 years and for individual entrepreneurs and legal entities 500,000-1 million rubles or suspension of activity for up to 90 days.

2/Criminal Liability

If a violation of the sanitary and epidemiological rules, by negligence, resulted in a massive illness or poisoning of people or posed a threat of same, the offender could face 2 years in prison\(^{32}\) and, if by negligence, causes the death of a person – this could be up to 5 years.\(^{33}\) If 2 or more people died, the maximum penalty could be imprisonment for 5 to 7 years.\(^{34}\)

Before the introduction of these amendments to the Russian criminal law, liability for violation of sanitary-epidemiological rules only occurred if such violation, caused by negligence, resulted in mass illness, poisoning of people or death of a person.

In accordance with the new law, only the threat of the spread of mass disease was enough to prosecute violators.

Criminal liability for violation of sanitary and epidemiological rules that created a threat of such consequences could occur only if this threat was real, namely when the consequences were not as a result of measures taken by the authorities, medical workers or other people to prevent the spread of the disease, or resulting from other circumstances that were independent of the will of the person who violated these rules.\(^{35}\) If an infected person left hospital and took used public transport, then such actions could theoretically lead to criminal liability.

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33 Part 2 of Art. 236 of the CC RF.
34 Part 3 of article 236 of the CC RF.
35 Review on selected issues of judicial practice related to the application of legislation and measures to counteract the spread in the territory of the Russian Federation of a new coronavirus infection (COVID-19) No. 2 (approved by the Presidium of the Supreme
Failure to Comply with the Rules of Conduct when Introducing High Alert

A new law\(^{36}\) introduced administrative liability for failure to comply with the rules of conduct when introducing a high alert on the territory in which there was a threat of an emergency or in the emergency zone.\(^{37}\) It could be violation of self-isolation by individuals who had to stay home, in accordance with the act of the authority of the relevant constituent entity of the Russian Federation.\(^{38}\)

The new article provided for the following sanctions: for individuals - a warning or a fine of 1,000-30,000 rubles; for officials - 10,000-50,000 rubles; and for legal entities - 100,000-300,000 rubles.\(^{39}\) In the event of a repeated violation, as well as if such actions entailed harm to human health or property, increased liability was available.\(^{40}\)

Spread of Fake Information about COVID-19

1/ Administrative Responsibility

Article 13.15 of the AC RF “Abuse of freedom mass information” was supplemented by 2 new parts, making it possible to bring administrative liability for legal entities disseminating false information via the media and information and telecommunication networks (as per the Internet) knowingly producing inaccurate information about the circumstances that posed a threat to life and people’s safety and/or measures taken to ensure the safety of the population and territories, methods and methods of protection from these circumstances. These violations attracted a fine of between 1.5 million to 3 million rubles.\(^{41}\)

If the dissemination of such information resulted in the death of a person, harm to human health, massive violation of public order or public safety, then the fine could be from 3 million to 5 million rubles.\(^{42}\)

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36 Federal Law of April 1, 2020, N 99-FL.
37 Article 20.6.1 of the AC RF.
38 For example, in Moscow it is the Decree of the Mayor of Moscow dated March 29, 2020, No. 34-UM “On Amendments to the Decree of the Mayor of Moscow dated March 5, 2020, No. 12-UM”.
39 Part 1 of article 20.6.1 of the AC RF.
40 Part 2 of article 20.6.1 of the AC RF.
41 Part 10.1 of article 13.15 of the AC RF.
42 Part 10.2 of article 13.15 of the AC RF.
2/Criminal Liability

For individuals, the new law provided for **criminal liability for the dissemination of knowingly false information:**

- about the circumstances that pose a threat to the life and people’s safety (epidemics, disasters, other emergencies, including the circumstances of the spread of COVID-19 in the Russian Federation), and about the measures taken to ensure the safety of the population and territories, measures and ways of protection against these circumstances - shall be punishable by a fine of 300 thousand to 700 thousand rubles to restriction of liberty for a term of up to 3 years\(^{43}\)

- socially significant information that caused grave consequences (harm to health, death of a person or other grave consequences) - the maximum sentence of imprisonment is up to 5 years\(^{44}\)

One of the conditions for the onset of criminal liability was the dissemination of knowingly false information under the guise of reliability. Misrepresenting false information as reliable could include forms, methods of its presentation (links to competent sources or statements by public figures), the use of false documents, video and audio recordings or documents and records related to other events. Knowingly false information includes information that does not correspond to reality, where the truth was known to the person who disseminated the falsehood.\(^{45}\)

The adoption of innovations aimed at strengthening administrative and criminal liability for violations of sanitary and epidemiological rules improved the mechanisms for protecting people from the threat of the spread of COVID-19 and other infectious diseases, and increased social responsibility, thereby ensuring the prevention of the spread of mass diseases.

\(^{43}\) Article 207.1 of the CC RF.

\(^{44}\) Article 207.2 of the CC RF.

\(^{45}\) Review on selected issues of judicial practice related to the application of legislation and measures to counteract the spread in the territory of the Russian Federation of a new coronavirus infection (COVID-19) No. 2 (approved by the Presidium of the Supreme Court of the Russian Federation on April 30, 2020).
2. Measures Aimed at Organizing the Provision of Medical Care during a Pandemic

2.1 Temporary Changes in the Organization of Medical Care

As a result of changes to federal legislation, in connection with the prevention and liquidation of emergency situations, the Government of the Russian Federation was vested with additional powers, including establishing the specifics of implementing the federal program of compulsory medical insurance, in the event of a threat of the spread of diseases that poses a danger to others. Based on these powers, the Government adopted a set of measures on the organization of medical care, which adjusted the rules for the provision of medical care until the end of 2020.47

The regional leaders were given the right to increase the waiting time for non-essential, planned medical care, which had been established in the states’ guarantees of free medical care for citizens. The procedure for sending citizens to receive planned medical care recognised the need to ensure an adequate level of organising planned patients in the context of re-profiling a number of medical organizations required to work with patients with coronavirus infection.

To ensure the safety of patients and medical workers, the Ministry of Health recommended that citizens postpone non-essential planned medical care both in outpatients and inpatients, in the absence of a threat to their life and health. The Federal Ministry of Health charged regional health authorities with the obligation to monitor possible violations in the provision of medical care, indicating that it is unacceptable to arrange additional places for the treatment of patients with new coronavirus infections that risks the health of patients with other diseases, and in conditions of removal or relaxation of restrictions, patients with COVID-19 should not be denied hospitalization.49

47 Decree of the Government of the Russian Federation of April 3, 2020, N 432 “On the features of the implementation of the basic program of compulsory health insurance in the face of the threat of the spread of diseases caused by a new coronavirus infection”.
48 Clarifications of the Ministry of Health of the Russian Federation of April 8, 2020, “Clarifications of the Russian Ministry of Health regarding the provision of planned medical care”.
To ensure the safety of patients, preventive medical consultations were temporarily suspended. The Ministry of Health recommended that the regions make decisions on the temporary suspension of routine immunization of children within the framework of the National Calendar, based on the prevailing epidemiological situation. When deciding whether to continue vaccination, as recommended by the WHO, “Guidance on routine immunization during the COVID-19 pandemic in the WHO European Region”. It is necessary to provide isolation and restrictive measures to minimize the possibility of exposure to COVID-19.

With the current epidemiological circumstances, there was a decreased level of preventive measures in the healthcare system, including dispensary observation and preventive examinations. There were risks associated with the need to redistribute the volume of planned care and certify adequate direction of non-essential planned patients while managing appropriate reassignment of specific medical organizations to work with COVID-19 patients.

2.2 The Organization of Work of Medical Workers and Medical Organizations Working with COVID-19

The Ministry of Health of the Russian Federation made temporary changes to the procedures and principles outlining the work of medical organizations to reduce the incidence of COVID-2019 infections. Federal Remote Consultative Centers were established and the regions instructed to create similar centers in the territories. They organized remote seminars for medical workers, on the diagnosis and treatment of new coronavirus infections, and round-the-clock consultations for the regions to identify individuals with suspected COVID-19. The Ministry of Health determined the minimum requirements for medical activities aimed at the prevention, diagnosis and treatment of new coronavirus infections.

52 Order of the Ministry of Health of the Russian Federation of March 19, 2020, N 198n “On a temporary procedure for organizing the work of medical organizations in order to implement measures to prevent and reduce the risks of the spread of a new coronavirus infection COVID-19”.
Issues regarding recruitment of specialist doctors, to work with the new coronavirus infections, were in the spotlight of the national health system. The Ministry of Health established a moratorium on obtaining specialist certificates and certificates of accreditation for specialists throughout 2020, with the validity period of expiring documents automatically extended by a year. The Ministry of Health allowed people with a certain level of medical and pharmaceutical knowledge to work in a pandemic during the pandemic. Individuals allowed to work with ordinary patients included:

- medical and pharmaceutical workers without accreditation (just submit an education document);
- clinicians, after completing a 36-hour training course, as trainees under the supervision of a specialist physician;
- graduate students with a secondary medical education, after completing a 36-hour training course, as secondary nurses under the supervision of a senior nurse; and
- People who had a medical education in Russia but had not worked for the last five years, after completing a 36-hour training course as a trainee or paramedical staff under the supervision of a doctor / nurse;

These same people, subject to additional requirements, could arrange a special unit for new cases of coronavirus infection.

If the epidemiological situation deteriorated, non-specialized specialists could be involved, following 36-hour training, to assist patients with COVID-19. They could assist under the supervision of a specialist. The heads of medical organizations were required to determine the composition of the doctors who provided care to patients with COVID-19.54

Unprecedented measures were adopted to mobilize health workers to ensure smooth operation in the pandemic. It was necessary to employ temporary

53 Order of the Ministry of Health of the Russian Federation of April 14, 2020, N 327n “On the specifics of admitting individuals to carry out medical activities and (or) pharmaceutical activities without a specialist certificate or a certificate of accreditation of a specialist and (or) for specialties not provided for by a specialist certificate or certificate of accreditation of a specialist”.

54 Order of the Ministry of Health of the Russian Federation of April 29, 2020, N 385n “On Amending the Order on the Temporary Procedure for Organizing the Work of Medical Organizations”. 
procedures for attracting non-core specialists, after additional education and training, including university medical students.

2.3 Government Support Measures for the Health System during a Pandemic

The President of the Russian Federation by decree, before the adoption of the relevant federal law, introduced a mechanism for social insurance and appointed additional lump-sum insurance payments to medical workers working with patients who had a new coronavirus infection or suspected COVID-19.55 The insurance payment was a lump-sum and paid according to the results of the investigation of the insured event (according to the rules of the Labor Code of the Russian Federation). Complementing other social insurance payments, the size of the payments depended on the scale of the consequences. The death of a medical worker resulted in payment of approximately 2.7 million rubles, Disability of a health care worker, consequent to transferred COVID-19, resulted in a payment of - from 680 thousand to 2 million rubles and with temporary disability (without the onset of permanent disability) - 68 thousand rubles. The source of payment was also determined to eminate from intergovernmental transfers from the federal treasury. It is likely that a more detailed regulation of the mechanisms for financial support of payments will require a federal law. The Presidential Decree was adopted based on Article 80 of the Constitution of the Russian Federation.

A package of state support measures provided for payments to medical workers for special working conditions and additional workloads when dealing with patients with COVID-19. Those medical workers who received a stimulus payment was established by the local regulatory act of the medical organization. The list couldalso be approved by the regional Ministry of Health. This payment was initially recommended for each month, from the beginning of the provision of medical care, for the time actually worked (with the exception of periods of absence of a medical worker from the workplace for appropriate reasons, including illness, vacation or other cases, as stipulated by law).56

Necessary amendments were made to the regulation of the payment mechanism.57 The previous wording - “a local act of a medical organization

55 Decree of the President of the Russian Federation of May 6, 2020, N 313 “On the provision of additional insurance guarantees to certain categories of medical workers”.
57 Decree of the Government of the Russian Federation of May 15, 2020, N 678 “On amendments to the Rules for the provision in 2020 of other inter-budget transfers”.
establishes the amount of payment for actually worked time” - generated many regional interpretations calculated based on the minutes spent next to the patient. Medical workers received very small amounts of incentive payments and the Ministry of Health of the Russian Federation considered such accrual of payments as an “incorrect interpretation”. Payments should have been based on the risk of working with patients with COVID-19 and were to be paid in full, regardless of the number of shifts and/or hours, if the employee worked in accordance with the established schedule. The Ministry of Health demanded that the governors recount and reimburse medical workers the correct amount of incentive payments without accounting for the “actually worked hours” and report correspondingly. Medical workers who have not received the due payments could complain to the Ministry of Health through the public services portal.

Among the general packages of state support for the health care system, an “accelerated” mechanism for the social insurance of medical workers was introduced and incentive payments were provided for special working conditions and the added risks when working with COVID-19 patients.

3. The Legal Status of the Patient during a Pandemic

Patients, not limited to those diagnosed with COVID-19, were the most vulnerable group, in terms of both medical and legal repercussions in the healthcare sector. Additional supportive and restrictive measures were introduced to find a balance between preventing the spread of infection (protecting the health of the entire population) and respect for human rights. The recent changes in Russian law required an appreciation of whether the patient’s legal status and basic rights were left intact.

3.1 Support Measures for Patients: General

When the first coronavirus infection was detected in Russia (before the introduction of the high-alert mode), the healthcare sector’s federal executive body adopted general explanations on priority areas in the organization and implementation of medical care.

58 Letter of the Ministry of Health of the Russian Federation of May 16, 2020, N 11-0/1/2-6574.
A temporary procedure, for the remote issuance of sick leave certificates was introduced for all people returning from abroad.\textsuperscript{59} Prescription drugs were allowed to be obtained by relatives, friends and volunteers. The developed electronic coronavirus service was launched, providing the opportunity to determine a citizen’s level of risk of infection and guiding him/her accordingly.\textsuperscript{60} It was recommended to prescribe medications with maximal permitted quantities amounts and calling patients with chronic diseases.\textsuperscript{61}

Some norms were not innovations, rather they were simply “lost” in the entire array of existing legislation and were not practically implemented. Unlimited to this period of pandemic, the attending physician could prescribe medications with a long validity period: from 15 days (narcotic and psychotropic drugs), to 90 days (for citizens entitled to free drug supplies or at a discount) and up to 180 days (for citizens with chronic diseases).

There were additional guarantees for patients, parallel to the application of restrictive measures.

The pharmacy organizations’ remote sales and retail distribution of medication became a norm.\textsuperscript{62} The demand for such a legislative provision was voiced by the public for a long time with the current epidemiological situation accelerating its implementation. The rights of the subjects and possible legal risks, with clarification of requirements for the pharmacies’ online platforms and organization of delivery were elucidated. Not all pharmacy institutions automatically acquired the authority to carry out distance trading which was restricted to those that received the appropriate permission from Roszdravnadzor. Prior to the pandemic, online sales for prescription drugs, narcotics, psychotropics and alcohol-containing drugs with a volume fraction of ethyl alcohol of more than 25% was impossible. In an emergency and/or when there was a threat of the spread of a disease that posed a danger to others, the Government could execute a temporary order permitting the sales and

\textsuperscript{59} Temporary procedure for registration of sick leave http://www.consultant.ru/document/cons_doc_LAW_348460/.

\textsuperscript{60} Information from the Ministry of Health of Russia “The Ministry of Health of Russia has launched an electronic coronavirus service for citizens”.

\textsuperscript{61} http://www.consultant.ru/document/cons_doc_LAW_348636/.


delivery of the above prescription drugs (paragraph 9). It is currently valid until December 31, 2020.

The approach to the online sale of medicines expanded the possibilities of electronic commerce and provided medicines, not only under the current restrictive measures, but also post-pandemic to address patients’ right to quality and availability of medical care.

Lacking guidelines at the beginning of the pandemic, some individuals were more vulnerable to disabilities, potentially caused by COVID-19. The authorities established temporary procedures for obtaining disability status: the initial examination was carried out in absentia and the status of a disabled person was automatically renewed for 6 months. The procedure for establishing disability remained a prominent issue for Russian patients, especially when considering the dependence of preferential drug provisions and the physical/health status of a “disabled person”. Many patients awaited the above changes, including the transition to electronic document management, and new opportunities to exercise their rights, including the hope for prolonging such services post-pandemic.

Another developing area was the introduction and development of telemedicine consultations. This has become especially relevant for some large regions that are most affected by the pandemic and were forced to introduce additional restrictive measures (such as requiring passes for moving around the city). In Moscow, with the support of the regional health authority, telemedicine consultations were already in use, although limited to patients with COVID-19 sufficiently mild to be treated at home. At the federal level, such a legal regulation has not yet been introduced - the bill is under consideration by the legislative body and provides for telemedicine (without special restrictive measures) only in emergency situations and when there is a threat of the spread of a particularly dangerous disease. Telemedicine has a

63 Ibid.
unique potential aimed at improving the quality and accessibility of medical care for patients and its immediate implementation would be welcomed. There is concern over the “slowdown” of its introduction, at the federal level, citing the length of the adoption procedure (especially by comparison with the timing of the introduction of restrictive measures) and the inclusion of additional and sometimes unreasonable conditions that are most apparent during critical situations (such as a pandemic). This includes the possibility of using telemedicine consultations with a doctor only from his workplace during self-isolation periods and the lack of an appropriate doctor to diagnose or write a prescription, without in-person consultations when re-profiling all medical institutions for COVID-19.

The state responded to the existing legal realities and embodied new mechanisms for the implementation of the established rights of patients in the “letter of the law”. The concern remains the actual implementation of the established measures and their real ability to smooth out the conflict between private and public interests: A question is raised: what were the reasons for the delay of these supportive measures pre-pandemic for the rights of patients?

3.2 Patients with COVID-19: Save Lives and Preserve their Rights

In addition to the supportive standards introduced in relation to patients, some categories of patients were subjected to restrictive measures. Patients with COVID-19 had to deal with legislative innovations restricting constitutional rights, including its immediate inclusion in the list of diseases that pose a danger to others.68

After a diagnosis of mild symptoms is established or after recovery in stationary conditions, a patient with COVID-19 and their cohabitants, citizens with a suspected presence of COVID-19 and citizens with a manifestation of acute respiratory viral infection and other infections, are all subject to electronic monitoring of their locations (through an application on their mobile phone) - the main resource of interagency interaction between government bodies and a fixator for violation of legislative norms. Such patients lost the right to refuse the monitoring or replace it with an alternative measures although the authorities claim complete safety of the information and privacy.69 Given

69 Order of the Moscow Department of Information Technologies dated April 29, 2020, N 64-16-186 / 20 “On approval of the Procedure for applying electronic monitoring technology of
the haste of introduction and the lack of a personalized approach (the norm is relevant not only for patients with COVID-19, but also for at-risk groups), there is a potential risk of self–medication as well as a disproportionate restriction of the right to privacy, especially in those with suspected COVID-19 infection. The introduction of electronic monitoring is not yet mandatory for all regions of Russia and the decision on the need for its introduction, as well as many other restrictions, remains with the heads of the Russian regions.

The inclusion of COVID-19 on the list of diseases that pose a danger to others automatically provided the opportunity for people suffering from its infection to undergo medical intervention without personal consent nor that of a parent or legal representatives (paragraph 9 of article 20)\textsuperscript{70}. This was reinforced by possible forced isolation and hospitalization of all the above categories of people, besides a person with a clear diagnosis (Article 33).\textsuperscript{71} The norms under consideration were not new to Russian legislation. Certain categories of diseases had clear legal mechanisms already developed for implementation in appropriate scenarios, including all entities subject to the norms (including active tuberculosis, the process of introducing forced intervention is fixed at the level of a separate federal law).\textsuperscript{72} The procedure was enshrined in the recommendations of the chief sanitary officer of the Russian Federation, which raised some doubts about the formal (not federal law) and substantive (mechanism and areas of responsibility not detailed) constitutionality of the innovation. The Supreme Court of the Russian Federation already confirmed the existence of such powers for the chief sanitary doctors and their deputies in one of their reviews,\textsuperscript{73} despite the lack of an optimal functioning model.

It seems obvious that the introduction of adaptive mechanisms to monitor COVID-19 patients into the regulatory framework is logical and mandatory to protect the health of the entire population. It remains important to comply with current legislation, in order to prevent potential and future legal uncertainties and human rights violations.


\textsuperscript{71} Federal Law N 52-FL “On the Sanitary and Epidemiological Well-Being of the Population”.


\textsuperscript{73} Review of selected issues of judicial practice related to the application of legislation and measures to counteract the spread of the new coronavirus infection (COVID-19) No. 1 in the Russian Federation, approved by the Presidium of the Supreme Court of the Russian Federation on April 21, 2020.
3.3 Persons with Chronic Illnesses are Hostages of a Pandemic

Due to the rapid increase in the number of patients with COVID-19 in Russia, priority public health efforts were committed to the fight against infection. Patients with chronic and rare diseases remained in a more vulnerable position and there was not, and has not been, enough financial support, nor manpower to assist their needs. The introduced universal restrictions made it difficult for such patients to receive high-quality and affordable medical care: more than 62% of respondents experienced difficulties in providing medicines during a pandemic.\textsuperscript{74}

Despite the norm introduced at the federal level, providing patients with drugs on an outpatient basis remotely, its potential has not yet been fully realized. In the early days of the high alert, many patients received unreasonable refusals due to inaccessibility of medical institutions, leaving people without vital medications. To address this, a large-scale drug provision was organized in large cities, but some regions were still not adequately prepared and forced patients to visit hospitals (converted for COVID-19) and pharmacies. Supporting the remote provision of drugs, as well as for long-term prescriptions, remained only a recommendation for the attending physician at the federal level and failed to receive emphasis during this pandemic. A “shift” of state responsibility to the attending physician seems unjustified and has become an obstacle to the proper implementation of the established norm.

At the regulatory level, planned medical care was limited in stationary conditions (day and round-the-clock).\textsuperscript{75} In this period of high preparedness, planned medical care could be organized only if there was a referral for hospitalization issued by the attending physician, the regional Ministry of Health or the federal executive body (paragraph 1.11). In all other cases, patients could be rejected due to the epidemiological situation, without consideration of all the possible risks for patients.

After some time, the norm was supplemented by a list of nosologies, people with whom they could receive full inpatient care. These included oncological, cardiovascular, endocrinological diseases and those on dialysis. They were

\textsuperscript{74} How a pandemic is experienced by patients with chronic diseases. https://vademec.ru/article/otrazhenie_sleduet_-kak_pandemiyu_covid-19_perezhivayut_patsienty_s_khronicheskimi_zabolevaniyami_/.

\textsuperscript{75} Order of the Ministry of Health of Russia dated 19.03.2020 N 198n “On a temporary procedure for organizing the work of medical organizations in order to implement measures to prevent and reduce the risks of the spread of a new coronavirus infection COVID-19”.
forced to dispute the legality of the introduced rules as the list of diseases was completely new and its hasty preparation failed to include some rare diseases, for which medications were essential.

A month after the imposition of the rules, the Federal Compulsory Medical Insurance Fund has stated that the postponing of planned hospitalization of inpatient did not apply to patients with conditions and diseases that endanger their life and health. The Fund expanded the restrictive list of the introduced illnesses, in order to avoid illegal refusals to provide medical care, but since this was not implemented in the legal act, one cannot exclude the possibility that some patients will encounter this problem.

Another obstacle for patients was the requirement to take an antibody-analysis for COVID-19, and in some regions being forced to pay for such an analysis. Learning of this perverse practice, the Compulsory Medical Insurance Fund accepted clarifications that refusals to carry out planned hospitalizations, without a certificate of COVID-19, would qualify as unreasonable refusals to provide medical care to insured individuals.76

People suffering from other diseases are currently a most vulnerable. A main function of public authorities is not only a prompt and strategic response to the current situation, but also the introduction of a response for uniform application and practice. It is propose to supplement the legal regulation (Order of the Ministry of Health No. 198n) with provisions for hospitals’ emergency medical responses to apply for patients with serious illnesses to with a standardized approaches and to consolidate the resources and guidelines for greater availability of telemedicine technologies.

The role of legislative innovations was determined by the number of scenarios and the real impact on the legal field and patients. Some patients are trapped: they received necessary supportive measures, yet encountered difficulties in benefiting from their implementation and the tightened control of the restrictions introduced, which required the adoption of federal laws and regulations (and not conclusions and clarifications that are not normative) to prioritize protection and advocacy of human rights and the patient’s legal status.


**Conclusion**

The state is in a pandemic and has been forced to take a series of measures aimed at restricting the rights and freedoms of its citizens to achieve the public good - as guided by the national and supranational legislations. The issue of maintaining a balance between private and public interests persists, expressed through the proportionality of restrictions and introduction of supportive measures for vulnerable communities.

In the Russian legal system, a certain level of legal uncertainty remains due to the current epidemiological situation and forced operational restrictive measures.

It is very important not only to respond promptly to the current critical circumstances with the adopted draft laws, but also to keep under control their further implementation and promotion of human rights and freedoms.

Even in the conditions of the global crisis, the legal system should be ready for the prompt introduction of additional and appropriate regulations and the development of optimal functioning models, balancing consistency with existing legislations and the translation of global standards. An important task, in the development and implementation of novel legislation, is to find a balance between personal rights of the individual (maintaining the protection of his/her legal status) and protection of public health (preventing the spread of infection).

There is a need for a constructive dialogue between the authorities, society and the public to protect the rights of citizens, improve the quality of healthcare and effectively combat the pandemic.

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TURKEY
COVID-19 AND TURKEY: THE HEALTH INFRASTRUCTURE OF TURKEY AND NATURE OF PRIVACY IN A PANDEMIC

Arda A*, and Arda B**

Abstract: This article examines Turkey’s response to the Covid-19 pandemic, from the aspects of health infrastructure of the country, access to information and privacy. The following is provided in this article: the timeline of the pandemic including the administrative information; a relevant analysis of the health infrastructure of the country and some advantages of the infrastructure; and the right to access to information and the nature of privacy in a pandemic.

Keywords: Covid-19; Pandemic; Turkey; Medical Law; Patient Rights; Health Infrastructure; Privacy; Access to Information

Covid-19 Pandemic in Turkey

As of 6th May, Turkey has the eighth-highest number of cases of Covid-19 infections, according to the data provided by Johns Hopkins University, Coronavirus Resource Centre. Even though the country has the eighth most cases in the world, it is on the thirteenth place in the world, ranking in terms of number of Covid-19 related deaths. As of 6th May, Turkey has 129,491 confirmed cases, 3,520 deaths and 73,285 recovered patients. A number of measures, to limit the spread of the coronavirus, have been introduced by the relevant authorities. The most radical of these measures, as of 6th May, is that there is a curfew in place, for the citizens aged over 65 and under 20 and those who have a chronical medical condition, such as chronic pulmonary diseases, asthma, chronic obstructive pulmonary disease (COPD), cardiovascular disease,

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1 Coronavirus Covid-19 Global Cases by the Centre for Systems Science and Engineering (CSSE) at Johns Hopkins University, available at: https://coronavirus.jhu.edu/map.html (last visited: May 6, 2020)
kidney disease, hypertension or liver disease\(^2\). The preventive measures have been introduced, by virtue of different administrative procedures, by different authorities of the government. The variety of the authorities that introducing measures, and the procedure that is followed worth a mention to understand the administrative framework of the Covid-19 spread in Turkey. Furthermore, the drastic measures beg the question of the acceptable boundaries of such impositions. This leads to the question of ‘where are the boundaries of privacy in the time of a pandemic?’

To provide a vivid illustration of the situation in Turkey, firstly, the relevant measures that were introduced by the Turkish authorities, will be looked into. Many administrative parts of the government worked in harmony and the administrative information, regarding the measures that have been taken, will be provided in the relevant timeline. Secondly, the health infrastructure of Turkey will be analysed together with some issues that may be seen as advantageous to understand the extent of Turkey’s response to the Covid-19 pandemic. Thirdly, the right to access to information and the nature of privacy in a pandemic will be discussed from the perspective of the implementations adopted in Turkey. These issues, perhaps being overlooked to a certain degree during a pandemic in some countries, the situation regarding these issues and the level of protection of the rights and privacy will be analysed from the perspective of Turkey.

A timeline of the pandemic in Turkey and the preventive steps taken by the authorities will be revealed below.

**The Timeline of the Covid-19 Pandemic in Turkey**

A number of public health measures have been taken by the Turkish authorities.

**1\(^{st}\) of February**

Turkey performed the initial Covid-19 related evacuation operation, by bringing 32 Turkish citizens plus 6 Azerbaijani, 3 Georgian and 1 Albanian citizens back to Turkey.\(^3\)

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3rd of February
Flights between China and Turkey were cancelled, starting from the 5th of February, as a result of advice provided by the Coronavirus Scientific Advisory Board. This decree was issued by the Ministry of Transport and Infrastructure.4

23rd of February
Turkey shut the border with Iran, by a circular order issued by the Ministry of Internal Affairs.5

29th of February
Flights to and from Italy, Iraq and South Korea were stopped by the Transportation and Infrastructure Ministry.6

11th of March
The first case of a person infected with Covid19 was announced by the Ministry of Health.7

12th of March
Education in elementary, middle and high schools was suspended for a week by the decision of the Ministry of Education. On the same day, Turkey’s Council of Higher Education (YÖK) announced that education in the universities would cease for three weeks.8

13th of March
Ministry of Transportation and Infrastructure stopped all flights to Germany, France, Spain, Norway, Denmark, Belgium, Austria, Sweden and Netherlands.9

15th of March
Ministry of Interior temporarily shut all bars and night clubs.10

17th of March
Museums and picnic areas were temporarily shut by the Ministry of Culture and Tourism.

18th of March
Ministry of Education announced remote education to start on the 23rd of March.11

19th of March
All conferences, panels, exhibitions, concerts and sporting events were suspended by a presidential decree.12 Mass Friday prayers got suspended and the mosques were to be kept shut on Fridays. This was ruled by the Religious Affairs Directorate of Turkey (Diyanet).13 All sports’ leagues were suspended by the Ministry of Youth and Sports.14

20th of March
All private hospitals were declared as pandemic hospitals by the Ministry of Health.15

21st of March
A curfew on people aged 65 and over was placed by the Ministry of Interior. The curfew included people with chronic illness.16 All hairdressers and barber shops were temporarily shut.17 The Ministry of Transport and Infrastructure announced that Turkey expanded the flight suspension to another 46 countries.18

22nd of March
The Ministry of Interior banned restaurants and cafes to have seating, allowing only delivery or takeaway.19

25th of March
All schools were suspended until the 30th of April by the Ministry of Education.20

26th of March
Higher Education Institutions Exam (YKS) were postponed to July and the entire spring semester was to be carried out entirely remotely by the Council of Higher Education.21

21 ‘Universities in Turkey to remain close for spring term, entrance exam postponed’
**28th of March**
Health workers were banned from resigning for three months, according to Ministry of Health.\(^22\) A village in Eastern Turkey was declared to be quarantined by the Ministry of Interior.\(^23\)

**29th of March**
Children were banned from entering bazaars and markets, as announced by the governor’s offices in Ankara and Istanbul.\(^24\) 12 more villages were quarantined by the Ministry of Interior.\(^25\)

**31st of March**
Turkish parliament extended an entry ban on foreign nationals into the country until the end of April.\(^26\)

**2nd of April**
Turkish Airlines flights were suspended.\(^27\)

**3rd of April**
Turkey’s 30 metropolitan cities and Zonguldak (a northern city, where respiratory illnesses are more common than any other city due to mining

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activity) were quarantined for 15 days by the Ministry of Interior.\textsuperscript{28} Existing curfews were enhanced to include people under the age 20 and over the age 65.\textsuperscript{29} Wearing face masks in public areas was mandated.\textsuperscript{30}

4\textsuperscript{th} of May

A press statement, made by the President after a cabinet meeting, which indicated that the return to normal life will evolve gradually. A few hours of curfew relaxation and the reopening of barbershops and shopping malls, respecting some restrictions was announced. On May 10, citizens, older than 65 and currently subject to a curfew will be allowed to go out for four hours adhering to social distancing rules. The same measure will apply to children and young adults, under 20, who are currently subject to a curfew. This will be applicable as ‘one age group per day.’\textsuperscript{31}

Health Infrastructure of Turkey: Some Advantages

The current population of Turkey is 83 million.\textsuperscript{32} The average age of the population is 31 and the twenty five percent of the population is under the age 15, which makes Turkey a young country.\textsuperscript{33} The percentage of the citizens who are above the age 65 is 8.8% which is 0.1% lower than the world average and 11.3% lower than the EU average.\textsuperscript{34}

\begin{itemize}
\item \textsuperscript{32} Turkish Statistical Institute, available at: http://www.tuik.gov.tr/HbGetirHTML.do?id=33705
\item \textsuperscript{33} ‘\textit{Turkey still has a young but aging population}’, Hurriyet Daily News, November 15, 2020, available at: https://www.hurriyeteddailynews.com/turkey-still-has-a-young-but-aging-population-148739 (last visited May 4, 2020)
Despite having a young population, Turkish citizens often have doctor’s appointments as health services are quite accessible. This situation is perhaps creating a considerable amount of circulation of patients and medical staff within hospitals. Hospitals in Turkey are almost always busy but have high capacity of critical care beds and the occupancy rate of the critical care beds has never been an issue in the country.

According to the statistics, released by the Ministry of Health, the number of applications to have a doctor’s appointment was 782 million in 2018. The numbers relevant to the health infrastructure, in 2018, was as follows: total number of doctors 153,128; total number of health personnel 1,016,401; total number of hospitals 1,534; the number of applications to have a doctor’s appointment per person on average 9.5; critical care bed capacity 38,098; and the occupancy rate of the critical care beds 66.9%. There are a considerable number of medical imaging facilities in Turkey and in 2018, the number of MR devices was 915 and the number of CT devices was 1211.

According to the data from the Ministry of Health, Turkey, as of 6th of May, has conducted approximately 35,000 tests a day since the beginning of the pandemic. The total number of Covid-19 tests completed in Turkey, as of 6th May, 2020, was 1,204,421, according to the daily data shared by the Ministry of Health. There has always been considerable debate regarding the doctor to patient ratio in Turkey. It is considered as ‘routine’ for a doctor, in Turkey, to see 60 to 80 patients per day. Taking this issue into account, the situation concerning the Covid-19 epidemic has been tolerated considerably well by the doctors in Turkey.

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38 Coronavirus Daily Table Turkey, Ministry of Health, accesible at: https://covid19.saglik.gov.tr/ (last visited May 2, 2020)
There was no published pandemic emergency plan in place for the procurement or allocation of resources and coordination of scientific and political discourses in Turkey. On the other hand, provisions that are regulating the preservation and improvement of public health were set out even in the Public Health Law,\textsuperscript{40} which dates back to 1930 and constitutes one of the initial pieces of legislation of the Republic of Turkey. Public Health Law sets out mandated reportable communicative diseases, how to report these and provisions regarding contagious disease and quarantine. This particular piece of legislation had been subject to many modifications and supported by other supplementary administrative instruments and now is up-to-date and the methods of implementation of it are clear.\textsuperscript{41} Even though Turkey did not have a pandemic emergency plan in the modern sense, this guideline, spanning 90 years, shed light on the methods to be followed in the situation of a pandemic.

\textbf{The Diameter of the Peephole: Right to Access to Information and Nature of Privacy in a Pandemic}

On the 6\textsuperscript{th} of April, China reported zero daily deaths from Covid-19, for the first time since January.\textsuperscript{42} China took undeniably strict measures to limit the spread of the virus. It is evident that some instruments are available to the Chinese government that are not applicable in some other countries. 59 days after the lockdown was initially introduced, China started stepwise relaxation of some measures. The Chinese people’s ability to enjoy their freedom is subjugated by phone applications (Apps), which are now seen as a crucial method of management of Chinese citizens by the Chinese government.\textsuperscript{43} The Chinese tracking Apps generally work with a Chinese identification (ID) number and their users consent to share their location data, lacking an explanation regarding the way in which such data is processed.\textsuperscript{44} Furthermore,

\begin{itemize}
  \item \textsuperscript{40} Public Health Law 1930, available at: https://www.mevzuat.gov.tr/MevzuatMetin/1.3.1593.pdf
  \item \textsuperscript{41} Circular regarding the Noticing and Reporting of Contagious Disease 2015/18, available at: https://hsgm.saglik.gov.tr/dosya/mevzuat/genelge/2015_18.pdf
  \item \textsuperscript{42} Davidson, Helen; \textit{China reports zero Daily deaths from Coronavirus for the first time since January}, April 7, 2020, The Guardian, available at: https://www.theguardian.com/world/2020/apr/07/china-reports-zero-daily-deaths-from-coronavirus-for-the-first-time-since-january (last visited April 9, 2020)
  \item \textsuperscript{43} Davidson, Helen, ‘\textit{China’s coronavirus health code apps raise concerns over privacy}’, The Guardian, April 1, 2020, available at: https://www.theguardian.com/world/2020/apr/01/chinas-coronavirus-health-code-apps-raise-concerns-over-privacy (last visited May 2, 2020)
  \item \textsuperscript{44} Yang, Yuan, ‘\textit{How China’s surveillance tech became my unlikely coronavirus ally}, April 7, 2020, Financial Times, available at: https://www.ft.com/content/0a59dec6-781f-11ea-9840-1b8019d9a987 (last visited May 2, 2020)
\end{itemize}
China is using face recognition technology that is 95% effective, in identifying people even wearing masks.\textsuperscript{45} Some issues regarding these tracking methods can be considered violations of privacy. One of the main concerns regarding the implementation of this system in China is that the consent of the individual would assumed to be given even though the individual may not really be aware what they are consenting for. The question, to be asked at the time of a pandemic, is the degree to which the privacy of the individual can be subject to violation. In China, the mobile Apps facilitate some degree of freedom to its citizens. However, if using these Apps is accepted as the chosen method to enhance freedom, then, these should not impair the privacy of the individuals and consent should be required with transparent explanation as to how the data will be processed, stored and used.

Some of the most crucial issues during a pandemic should be considered as exerting utmost efforts in ensuring the preservation of rights and privacy. This should entail an objective test where the requirements of public health justifiably impose some restrictions on the rights of the individuals. At the time of a pandemic, the right to access information gains greater significance correspondingly with the increasing necessity of transparency. The lessons that are learned from pandemics would provide invaluable guidelines for future pandemics and other struggles on a global scale. Taking this into account, the key elements to be kept in mind during a situation like this, in which epidemiology and the science of statistics contribute majorly, should be \textit{‘the accurate data collection and the analysis of accurate records by proper methods.’}\textsuperscript{46} Furthermore, as emphasized in the Evaluation Report of the Turkish Academy of Sciences on the Covid-19 pandemic, the initial issue concerning the distribution of accurate information would be \textit{‘to work with the expert member of the relevant departments and the members of other science departments, who can provide contribution on a multidisciplinary level.’}\textsuperscript{47} Accordingly, the Science Committee was established on the 10\textsuperscript{th} of January 2020, following China’s announcement of the coronavirus outbreak.

\textsuperscript{45} Yang, Yuan, \textit{‘How China built facial recognition for people wearing masks?’}, March 18, 2020, Financial Times, available at: https://www.ft.com/content/42415608-340c-4c0a-8c93-f22ced4cc2d6 (last visited May 2, 2020)


The Committee includes 31 member doctors and academics, who are experts on infections, microbiology, virology, internal diseases and intensive care. The Committee comprises members who are internationally respected in their individual fields. They have been following the developments regarding the Covid-19 pandemic and invaluably assisting the government. The Science Committee prepared an informative leaflet on the Covid-19 which was distributed throughout the country and expert doctors and academicians were constantly on the national television channels, trying to inform the public. From day one, Turkish citizens have been kept informed in a detailed way with daily press conferences, held by the Minister of Health, Doctor Fahrettin Koca, in which the numbers regarding the pandemic have been shared with the public and the questions of the members of the press have been answered. A very extensive informative campaign was pushed in Turkey. According to a national survey, conducted in early April, 78% of the participants indicated having enough knowledge regarding Covid-19 symptoms.

A balance between individual privacy and public health must be found during the pandemic. Evidently, the relevant data, collected from individuals is considered crucial to be able to contain the spread of the virus. However, not all data processing methods and reasons can be justified for the purposes of tackling the situation. Turkey introduced a contact-tracing App, designed to detect and inform whether an individual had come into contact with an infected person, by sending a notification such as ‘(X) days ago you have encountered a person who tested positive for Covid-19.’ The App merely informs the individual, by sending a notification regarding the contact and maintains the anonymity of the infected person. Prior to its introduction, the Chamber of Computer Engineers of the Union of Chambers of Turkish Engineers and Architects released a statement indicating their members’ concerns regarding the implementation of such a contact-tracing App. What brought forward

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51 ‘Saglik Bakanligi’na Cagri: Pandemi Izolasyon Takip Projesi’nin Amaclari ve Isleyis
as a concern was regarding the possibility of not revealing the purpose and rules of operation of the said phone App in a transparent manner. Some of the emphasized issues were that: all aspects of the functions, purpose and the expected benefits of the app to be shared openly with the public; that it should be emphasized that this is a method to be used only during the days of pandemic and hence to be a temporary method, the nature of the data to be collected while using the phone application and the location of the data to be held and how the security of this location to be provided should be clarified, information regarding the duration of keeping the collected data and methods regarding this data being deleted to be announced.\textsuperscript{52} With regards to mobile tracking Apps as such, the main demands of the experts draw the attention as these being safe in terms of data privacy and also being temporary in nature.

Two public announcements were made by the Personal Data Protection Authority in March 2020. It was announced, in relation to Covid-19 pandemic, that the Personal Data Protection Board will take the extraordinary conditions in the country into account for each application or data breach notification and will be aware that there may be delays in complying with the required periods of notification.\textsuperscript{53} This particular announcement signaled a degree of flexibility to be allowed during the current situation, with regards to compliance with periods regarding notice and report. The announcement provided the Personal Data Protection Board with a discretionary power which should be exercised, considering the background facts of each application individually.\textsuperscript{54} Perhaps a concerning issue is the vagueness of some terms included in the announcement, such as “delay.” The amount of time that is passed to be considered as an acceptable amount of delay and the operational realities and causes for that particular delay should be clarified by considering each application by the data controllers. It should be noted that, this was a considerably short public announcement and a second announcement was made a few days later.


\textsuperscript{54} Public Announcement of Personal Data Protection Authority under Covid-19 on 23 March 2020, Eyuboglu & Buyukatak Attorneys at Law, March 24, 2020, available at: https://
The second announcement emphasized the importance of the preventive steps taken by public and private organisations to contain the spread of the virus and indicated that these preventive steps often include an inevitability of processing of personal data.\textsuperscript{55} The second announcement elucidated the general principles of data protection regulations, with a special emphasis on the data minimisation principle. The other main issues that were touched upon were the lawfulness, transparency, privacy and the public announcement had also these issues as sub-headings. It was clearly indicated that the data processing to be done in compliance with the purposes of processing, in a limited way and also proportionally.\textsuperscript{56} The second announcement can be considered as more detailed than the former one and covered more aspects of data privacy in a pandemic.

\textbf{As a Result}

The Ministry of Health in Turkey, was established by Law no. 3 on the 3\textsuperscript{rd} of May, 1920, following the opening of the Grand National Assembly and during the course of the War of Independence. This illustrates that one of the priorities of the founders of the Republic of Turkey was health. The Republic of Turkey, as the follower of the Seljuk and Ottoman legacy, has maintained the continued state tradition of organisation of health services linked to cultural unity. While developing this structure over time, a western-oriented path has been followed in the organization of state and service policies. The developed health policies were also affected by the main trends in the world. Relevant to the Covid-19 pandemic, in Turkey, the following points can be stated; effective measures are taken just in time, these measures are applied at a very high rate, that the whole process is carried out in a scientific framework and that the recommendations of the scientific board are practised with precision. Furthermore, considering the country’s response to the pandemic, it can be argued that the right to access to information and the privacy of individuals were protected with the utmost caution during these unprecedented times.


UKRAINE
INSTITUTIONAL AND LEGAL ASPECTS OF HEALTH CARE
IN TIMES OF COVID-19: LEARNING FROM THE UKRAINIAN EXPERIENCE

Radmyla Yu. Hrevtsova*

Abstract: The paper discusses the changes in the Ukrainian institutional and legal landscape that have become critical with regard to the novel coronavirus disease (COVID-19) outbreak. Ukraine has faced the pandemic during the reforms of its healthcare system and others. Some of the institutional changes, aimed at resolving the burning issues and fulfilling political commitments (such as liquidation of the notorious health system institution with a branched structure, still responsible for the epidemiological safety, financing infectious disease units for the actually provided services) have shown underperformance, particularly in light of healthcare emergency preparedness. Some other changes (including introduction of medical self-governance) require boosting. The coronavirus crisis should serve as an impulse to changing the attitudes of the state and society towards healthcare workers who currently have to reclaim their rights, especially the rights to safe working conditions and proper remuneration and ensuring due protection and respect. Special attention shall be paid to legal substantiation of the development of innovations. This primarily relates to the use of telemedicine tools which may be essential for ensuring access to healthcare, both in everyday life and emergencies.

Keywords: Coronavirus Disease (COVID-19) Outbreak; Health Care Reform; Institutional Changes; Rights of Healthcare Workers; Telemedicine

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The health systems and economies of most countries are seriously affected by the SARS-CoV-2 pandemic. Though all working towards protection of health, the countries’ practices of responding to coronavirus disease (COVID-19) outbreak differ. For the developing countries, it is especially challenging to effectively address the pandemic. The experience of Ukraine may be of interest to researchers and policymakers of nations striving for political democracy and economic growth as well as those that have achieved these goals.

This paper is aimed at discussing the Ukrainian legal responses to challenges brought by the novel coronavirus infection; the institutional and legislative framework that determined the peculiarities of the taken measures and their implications; as well as the lessons one can learn from the Ukrainian experience.

**INTRODUCTION**

Ukraine inherited an extensive healthcare system from the Soviet Union. Although it was designed to ensure universal healthcare coverage, Ukraine’s health system was “*sclerotic and basically based on the Semashko model with very rigid public finance management procedures*” (Health Strategic Advisory Group, 2014). In modern conditions, it has become ineffective even with some incremental changes. The most recent attempt of reform was initiated in 2014, dealing with medical care and public health though the emphasis was on healthcare financing. Based on the “*money follows the patient*” principle, the primary care reform was completed. April 1, 2020 was determined as the starting point for the second stage of the healthcare reform (focusing on specialized care). Top Ukrainian healthcare officials declared the necessity of substantial changes to the overall reform and correction of any mistakes committed (Stepanov, 2020).

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5. Максим Степанов: Ми суттєво змінимо медичну реформу в Україні, враховуючи
with the healthcare reform. The goals, merits and challenges of the other reforms could not but affect the institutional and legislative framework of the Ukrainian health care system functioning. Ukraine encountered the SARS-CoV-2 pandemic and had to look for responses to the threat while staying in the uneasy reforming process.

BACKGROUND

In Ukraine, the first case of COVID-19 was confirmed on 3 March 2020. Without waiting for the wide spread of the infection, on 11 March 2020 the Cabinet of Ministers of Ukraine imposed the quarantine, prohibiting the attendance of classes and limiting mass gathering events. Initially the lockdown was planned from 12 March 2020 till 3 April 2020. In the middle of March, the work of companies and entrepreneurs presupposing customers’ visits was banned and most public transportation services were stopped.

On 2 April 2020, the lockdown was prolonged and containment measures were increased. Appearance in public places, without personal protective equipment (PPE), moving in groups of more than 2 people (with some exceptions) and visiting parks and public gardens were prohibited.

The lockdown lasted till 22 May 2020 (with easing of some requirements since 11 May 2020). As of 22 May 2020, 148 cases were confirmed, 12,975

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cases active, 6,585 people recovered and 588 people deceased. According to experts’ opinions, Ukraine’s containment measures were timely and kept the coronavirus disease (COVID-19) morbidity rate within the limits of a functioning healthcare system.

Since 22 May 2020, the so-called “adaptive quarantine” has been in effect, where “most restrictions are relieved but quarantine remains or severe containment measures are imposed in the regions with the high morbidity rate” (Cabinet of Ministers of Ukraine, 2020).

DISCUSSION

The coronavirus crisis has mirrored the existing institutional, legal and ethical issues and reached certain conclusions that could be of interest to an international reader.

Institutional and Infrastructure Capacities: “Momento Infectio”

Institutional and infrastructure capacities are prerequisites for preparedness for health emergencies at the national and territorial community levels. The situation around COVID-19 “has once again illustrated the importance of ensuring the institutional capacity and the quality of legislation in the sphere of health care” (Hrevtsova, 2020).

Institutional Changes

In Ukraine, institutional changes aimed at modernizing the national health system and resolving the pressing issues of social demand (such as elimination of corruption and enhancement of business environment) have been made. At the
same time, the core essence of the relevant institutions and legislative constraints appeared to be overlooked in the course of designing and implementing the changes apparent with the coronavirus disease (COVID-19) outbreak.

This relates, first of all, to liquidation of the State Sanitary and Epidemiological Service of Ukraine (SES) – the state authority responsible for “the implementation of the state policy in the sphere of population sanitary and epidemiological safety”15. The attitude towards the SES, shared by a part of the politicum and society, was well reflected in an official document stating that concentration of the activity of the SES “on the execution of total control” over economic entities “led to the deterioration of business environment in the country and did not further the improvement of the situation with the population morbidity rate”16. At the same time, functionality, branched structure and workforce capacity had made the SES a core element of the health emergency preparedness system.

Regardless of the fact that the existence of the SES and its competence were stipulated by law17 (!), in 2014 the Cabinet of Ministers of Ukraine issued the act whereby the SES was reorganized through its incorporation within the newly established State Service of Ukraine on Food Safety and Consumer Protection18. In 2017, after litigation proceedings, questioning the lawfulness of this reorganization and result of outlawing it19, the Ukrainian government finally liquidated the SES20. The powers of the SES were partly transferred to the State Service of Ukraine on Food Safety and Consumer Protection and, arguably, to the Ministry of Health of Ukraine21, including the State Institution “Public Health Center of the Ministry of Health of Ukraine.”

17 Vide supra., 15.  
Confusing terminology used by authors of relevant governmental acts resulted in collisions and gaps in legal regulation of the powers of the above authorities. Some researchers even believe that “the bigger part of the tasks of the state sanitary and epidemiological surveillance as well as that of the directions of the Ukrainian state SES system have not been transferred to any central executive authority” (Demchenko, 2020, p. 201)\(^2\).

Ukrainian laws still contain several provisions on the SES (that was liquidated) and/or those based on the existence and functioning of the SES. Some of them became critical when the introduction of COVID-19 containment measures appeared on the agenda. Article 29 of the Law of Ukraine “On the Protection of Population from Infectious Diseases” states that the issue of enforcing a quarantine shall be raised before the Cabinet of Ministers of Ukraine, based on the report of the Chief State Sanitary Doctor of Ukraine\(^2\). According to Article 32 of the Law of Ukraine “On Ensuring Population Sanitary and Epidemic Safety”, the Chief State Sanitary Doctor of Ukraine heads the SES\(^2\).

The position of the Chief State Sanitary Doctor that had “disappeared” together with the SES, was renewed by appointing Mr. V. Lyashko as “the deputy Minister of Health of Ukraine - the Chief State Sanitary Doctor of Ukraine” in March 2020\(^5\).

The functions of the Chief State Sanitary Doctor of Ukraine are certainly not limited to resolving technical and bureaucratic issues. The need of the renewal of the local “chief sanitary doctors” was unveiled and relevant appointments were made. The “renewal” of these positions, without reconstructing/construing the foundations, seems a temporary measure of dubious legality rather than a viable mechanism suitable for the performance of the tasks, related to sanitary and epidemic safety.

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24 Vide supra., 15.

What lesson can be learned from the outlined situation? What can be recommended for policy makers in Ukraine, and other countries, based on the discussed experience? The following three items seem critical to implement. When attempting to meet political and societal expectations, connected with the healthcare institutional landscape, emergency preparedness must be maintained. As mentioned in the annual report of the Global Preparedness Monitoring Board, in 2019, “while disease has always been part of the human experience, a combination of global trends, including insecurity and extreme weather, has heightened the risk. Disease thrives in disorder and has taken advantage - outbreaks have been on the rise for the past several decades and the spectre of a global health emergency looms large. If it is true to say “what's past is prologue”, then there is a very real threat of a rapidly moving, highly lethal pandemic of a respiratory pathogen killing 50 to 80 million people and wiping out nearly 5% of the world's economy” (Global Preparedness Monitoring Board, 2019)26. It is likely that this SARS-CoV-2 pandemic will not be the last (El Zowalaty, Jarhult, 2020)27. Institutional changes are not made immediately and those who introduce them often miss the coherent picture, failing to be aware of the organs accountable, and duly delimit their responsibilities. It is extremely important to have a “holistic vision” keeping the details in mind. Auditing the national legislation, to resolve the conflict of norms and fill in the gaps of legal regulation of health emergencies preparedness, seems worthwhile. Addressing the recently uncovered ineffective or lacking legal details, during this pandemic (COVID-19), may enhance quality of such legislation audit.

The Healthcare Infrastructure Optimization Lesson

Another system-related lesson deals with healthcare infrastructure capacities. While carrying out the health care reform, the process of “optimization of the structure of the hospital stock”28, namely the reduction in number of hospital beds to more effectively use the limited financial resources, was launched.

28 The Methodology for Ensurance of Hospital Stock Reckoning at 10,000.00 Population. Approved by the Order of the Ministry of Health of Ukraine No. 51 dated 01 February 2016. URL: https://zakon.rada.gov.ua/laws/show/z0269-16#n18.
Health care was supposed to be financed under the principle “money follows the patient.” This was to be extended on infectious diseases hospitals. The Ministry of Health of Ukraine pointed out that “departments of infectious diseases would be financed in the same way as other inpatient units – for the provided services.”\(^{29}\) It was planned to stop their financing at the expense of the state budget subventions at the second stage of the healthcare reform, that started on 1 April 2020. The reduction in number of infectious disease units and reprofiling of infectious diseases hospitals became highly probable. Healthcare officials have recently recognized that the coronavirus outbreak has shown that infectious disease hospitals should be financed for the preparedness to provide medical care but not based on the actually provided services (V. Lyashko, 2020)\(^{30}\). The preparedness to health emergencies and possibility to provide effective medical care should not be sacrificed to economic efficiency, since the population’s epidemic safety and individuals’ lives depend on it.

**The Quest for Professional and Ethical Guidance**

The containment measures were timely and Ukraine avoided a potentially much worse scenario. The indicated figures are far from showing the healthcare system’s implicit catastrophe. The preparedness to overloaded healthcare institutions and the decision on giving the priority in access to life-saving treatments should, however, be on the agenda.

The concept of “medical triage” has become widely known with this pandemic. Determining the concrete grounds for triage is unclear when considering hospital and especially intensive care.

The pieces of legislation that are effective in Ukraine are mostly focused on medical triage made at the prehospital phase or within the casualty (accident and emergency) departments\(^{31}\). The Standards of Medical Care “Coronavirus Disease (COVID-19)” provide a guideline for the primary screening of

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The issue of triage in intensive care units still requires proper determination – either at the level of normative acts or at the level of recommendations as suggested by the professional community. This is necessary “to relieve clinicians from a part of the responsibility in the decisions making process, which can be emotionally burdensome”, as pointed out in the Recommendations made by the Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI, 2020). It is also important with regard to protection of doctors from unsubstantiated bringing to responsibility for maltreatment as well as in view of protection of patients from unreasonable triage decision-making.

Who should determine such triage rules? The World Health Organisation (WHO) website detail their establishment by national healthcare authorities and by professional associations (WHO, 2020). These rules should be framed by the medical community or at least with its participation. If the legal tradition so requires, such rules shall have not only ethical but also legal force (for instance, the binding force that is given to the acts of the organs of professional self-governance that enjoy the powers delegated by the state). In Ukraine, there is no medical self-governance regardless of numerous legislative attempts. The current coronavirus crisis may stimulate the Ukrainian medical community to reclaim the rights pertaining to medical professionals.

**Healthcare Workers’ Rights Protection: Pandemic Urges Raising the Standards**

The Ukrainian legislation provides for several professional rights and privileges granted to healthcare workers, although a lot of issues arise during the exercise of such rights by medical professionals. Systemic violations of labor, social and professional rights of medical workers do occur (Hrevtsova, 2017).

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35 Гревцова Радмила. Захист прав медичних працівників: готовимося до самооборони?
The right to safe working conditions and the right to proper remuneration of labour are among the rights that are most commonly violated under the conditions of COVID-19.

The Right to Safe Working Conditions: Focus on the Provision of Personal Protective Equipment

When assessing the level of adherence to the right to safe working conditions, in the COVID-19 context, the insufficiency of personal protective equipment procurement (PPE), in healthcare facilities, must be discussed. The Center for Public Health, within Ukraine’s Ministry of Health, admits that this is a reason for the high rate of infection among medical personnel\(^{36}\). As of 22 May 2020, 2,020 healthcare workers were infected, 19.4 % out of the total infected\(^{37}\).

The current legislation of Ukraine provides for the obligation of the owner or the authorized body to ensure the employee safe working conditions that comply with the requirements of normative acts, including the availability of the necessary PPE\(^{38-40}\). Such requirements are contained in the Standards of Medical Care “Coronavirus Disease (COVID-19)” (Annex 6 “The Rational Use of Personal Protective Equipment”) approved by the Ministry of Health\(^{41}\). The type of PPE to be used depends on the conditions, target personnel and patients and the type of activity (such as provision of care to patients

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\(^{41}\) Annex 6 to the Standards of Medical Care “Coronavirus Disease (COVID-19)” (with changes). Vide supra, 32.
with COVID-19 and to patients with respiratory symptoms). Higher risks of contamination (as per inpatient facilities caring for patients with confirmed COVID-19) call for higher levels of protection. There are numerous incidents of contamination of healthcare staff who work at healthcare organizations or units that are not intended for providing care to patients with COVID-19. It may be necessary to use PPE providing greater protection than those stipulated within the requirements of the said Standards. Are there any legal tools to increase the “protection minimum”? The answer is “Yes” but the possibility and effectiveness of such tools depend on a couple of factors, including the employer’s readiness to make relevant changes to the collective labour agreement, concluded by and between the employer and the trade union or the employees’ representatives authorized by the labour collective of the healthcare institution (in case of the trade union’s absence), and the medical workers’ readiness to take measures aimed at the protection of their rights.

In the course of reform, healthcare facilities that had been budgetary institutions were transformed into communal non-commercial enterprises that allowed greater financial and managerial autonomy of healthcare providers. The Ministry of Health pointed out such advantages as the chief of the healthcare provider having greater freedom in disposal of assets and finances, determination of the organization chart, forming the staff policy and fixing the forms of remuneration that is allowed by the legislation. The use of such powers, by chiefs of healthcare providers, has only recently been formed. Effective engagement and interaction with the staff, listening to the voice of the labour collective and account for its needs, as well as the ability of such collectives to advance its rights, has become increasingly important. This is, to a large extent, true for the right to proper remuneration of labour.

42 See, for e.g.: Панчишин І. 67 працівників львівської лікарні швидкої допомоги захворіли на Covid-19 [Електронний ресурс] // ZAXID.NET. - 20.05.2020. - URL: https://zaxid.net/u_lvivskiy_likarni_shvidkoyi_dopomogi_na_covid_19_zahvorili_67_pratsivnikiv_n1502474?fbclid=IwAR3njknCnHzG1nLGg_iiiRao-eLXRyw18k2_9X4YPQgWejqrR3K1jK0vJX8.


**Healthcare Workers Remuneration: Legislation and Implementation**

In Ukraine, the remuneration of healthcare workers is far from standing in line with their qualifications and character of the performed work. In accordance with the data from the State Service of Statistics of Ukraine, on February 2020, the average salary of staff employees, in the sphere of healthcare, constituted UAH 7,471.00 (that approximately equal to $ US 304), while the average salary per the national economy constituted UAH 10,847.00\(^{46}\). The issue of low wages is especially acute for secondary and tertiary care which have not yet undergone reform. It has deteriorated with the novel coronavirus disease (COVID-19) outbreak which increased the risks the medical workers face while providing care to their patients.

At the end of March, the Supreme Rada of Ukraine and subsequently the state executive authorities gave grounds to increase payment to healthcare workers who take part in medical care for patients with COVID-19, providing for additional payments to such workers in the amount of up to 300 per cent monthly salary for March 2020 \(^{47,48,49,50}\). The normative efforts were initially quite chaotic necessitating correction.

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\(^{49}\) Act of the Cabinet of Ministers of Ukraine No. 331 dated 24 April 2020 “On Urgent Measures to Ensure State Financial Guarantees to Medical Personnel Caring of Patients with Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-CoV-2, and Proper Remuneration of Medical and Other Workers Who Care of Such Patients”. URL: https://zakon.rada.gov.ua/laws/show/331-2020-%D0%BF.

By May 2020, the Minister of Health Care informed that “we received a great many of complaints and letters related to the failures to fully pay the medical workers, the very workers who worked with those having COVID-19, and first of all the March payment was meant”\(^51\). Delays and even “manipulations with payments” (Stepanov, 2020) were reported to occur on behalf of local authorities and/or subordinated healthcare institutions managers\(^52\).

On 11 May 2020, the Prime Minister of Ukraine, D. Shmygal, explained that money was sent to regions but local authorities were governed by the document of the Ministry of Social Policy of 2003, instead of the new Act of the Cabinet of Ministers. That was why, regardless of the availability of funds in the regions, they failed to make necessary payments\(^53\). This underscores the importance of prioritization of quality of legislation, particularly those adopted in times of pandemic. Pieces of such legislation are to be adopted quickly and decisively, while the quality of legislation must be ensured by considering the broad administrative and legislative picture that will allow due understanding and implementation. There is evidence that in many cases the local authorities met the new challenges. As pointed out by deputy mayor of Borispil town, L. Panasenko, in Ukraine, it appears possible to restrain coronavirus “to a large extent due to the reform of decentralization and capacity of territorial communities and cities to take the responsibility and financial burden for combating the disease outbreak”\(^54\). The due execution of powers, in the sphere of healthcare, by local authorities and their powers over healthcare institutions management performance, have become of greater importance. The pandemic has attracted the attention of the state and municipal authorities as well as

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52 LB.ua. Степанов: затримки з виплатами потрійних зарплат медикам виникають з вини місцевої влади або головлікарів [Електронний ресурс] // LB.ua. URL: https://ukr.lb.ua/society/2020/05/02/456583_stepanov_zatrimki_z_viplatami.html.


elevated issues relating to the rights of healthcare workers and remuneration of their work. This should motivate the nation to address the problems both mid-pandemic and post-pandemic.

The Conduct of Medical Practice: Changes in the Legal Landscape

The coronavirus crisis affected the organizational, economic and clinical aspects of medical practice. It has influenced the provision of primary, specialized, inpatient and ambulatory care.

COVID-Related Limitations of Medical Practice

In Ukraine, constraints to planned hospitalizations and surgeries were imposed: they were substantiated by the necessity of “insurance of preparedness of healthcare institutions for providing medical care to people having the acute respiratory disease COVID-19 caused by SARS-CoV-2 coronavirus.” Even when it has become evident that sufficient numbers of hospital beds will be available for COVID-19 patients and quarantine restrictions lessened, the limitations on planned hospitalizations still remain in effect.

In addition to limitations, imposed by the Ukrainian government, additional restrictions were placed locally. In accordance with Article 30 of the Law of Ukraine “On Sanitary and Epidemic Safety of Population”, in cases of highly infectious disease dissemination, the local executive and self-government authorities are entitled to impose special conditions and labour regimes on

57 Vide supra, 55.
the appropriate territories\(^{60}\). For example, in Kyiv, the capital of Ukraine, the provision of dental services, except for urgent cases, was prohibited from 28 March\(^ {61}\) till 12 May 2020 \(^ {62}\). As of the last decade of May, most medical activities that had been restricted earlier on were renewed.

**Telemedicine: Ukrainian Realities in Times of COVID-19**

Certain changes in the customary “doctor-patient” relationship have occurred or still need to be introduced. They include: informing patients of the provision of medical care in the period of COVID-19 outbreak; obtaining the patient’s informed consent; and correction of the patient’s treatment plan, with regard to possible change (deterioration) of the epidemic situation and so on. The most notable change deals with telemedicine.

In March 2020, when Ukrainian health care authorities got concerned about the capacity of the healthcare system to ensure inpatient care, to people having severe cases of COVID-19, the Ministry of Health recommended to “increase the proportion of medical care provided via telemedicine” to healthcare institutions\(^ {63}\). That gave the impulse to diagnostics and treatment with the use of the telemedicine. The lack of relevant experience, among physicians and patients, led to incomplete appreciation of the essence and peculiarities of telemedicine tools. A number of steps, including legislative, have been made in Ukraine with regard to teledmedicine \(^ {64,65}\). The definition of telemedicine and its tools, as well as other basic items related to the introduction of telemedicine, were determined. In the prior introduced format, teledmedicine

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\(^{60}\) Vide supra, 15.


\(^{62}\) Enactment No. 41 of the Manager of Works on Liquidation of the Emergency Consequences “On Making Changes in Enactment of the Manager of Works on Liquidation of the Emergency Consequences dated 25.03.2020 No. 2 “On Measures on Liquidation of Consequences of the Emergency of the Regional Level Pertaining to the Category “Medical and Biological Emergencies” Code 20713 “Emergency Connected with the Acute Infectious Disease Outbreak” dated 12 May 2020. URL: https://drive.google.com/file/d/1i_1bwWj48op1MkYHTc6mDKwWZeFwsk/view.

\(^{63}\) Vide supra, 55.


was primarily directed at (and used for) the “doctor – doctor” relationships, exercised via “telemedical advice” and “telemedical concilium”. The “doctor-patient” relations were also mentioned in the relevant pieces of legislation. “Home teleconsulting”, supposed self-sufficient communication from patient to doctor, was not regulated well and used less often than the other tools. The types of healthcare services which may/should be provided via telemedicine, informing the patient of the peculiarities of the service provision via telemedicine, particularly of limitations and reservations; and fixation of informing the patient are among the issues that have remained unresolved.

Several doctors have a cursory view of legal requirements for the use of telemedical services because of the comparatively low incidence of telemedicine before COVID-19 outbreak. Ukrainian legislation in force determines that telemedical services shall be administered by healthcare institutions or doctors and private entrepreneurs licensed to conduct medical practice and use a special telemedical Internet platform. Many physicians started consulting patients via commonly used distance communication means with little concern of personal data protection and data integrity and on their own behalf. They were unaware that such consulting did not comply with the current legislation and could give grounds for claims and charges, especially in cases of actual or alleged infliction of damages to the patient.

While in health emergencies, telemedicine shall become an indispensable tool for providing universal access to quality medical services. Under certain circumstances, the use of telemedicine may instead lead to legal risks because of: insufficient legislative certainty; lack of explanations; and low awareness of the rules of telemedicine functioning. There are cases where doctors legally, but incorrectly, render “telemedical” services to non-COVID patients. There are also situations where telemedicine was provided for provision of outpatient care to patients with confirmed COVID-19.

In accordance with the Standards of Medical Care “Coronavirus Disease (COVID-19)”, a primary care physician who provides medical care for a patient with COVID-19 shall monitor (control) the patient’s status through the methods chosen by that physician individually (such as daily visits, through

66 In Ukraine, there are no individual licenses issued to physicians. The license for the conduct of medical practice shall be issued for a healthcare institution or a doctor registered as a private entrepreneur. Physicians may practice medicine either if they are employed by a healthcare institution or if they are registered as private entrepreneurs who obtained the license or are employed by such entrepreneurs.
telephone inquiry.)\textsuperscript{67} It is the primary care physician who makes the decision on the possibility of limiting the services rendered to the patient with COVID-19 to outpatient care. Such decisions may be based on distant communication with the patient. Such possibility is important in terms of decreasing the risk of COVID-19 patients’ infection of primary care physicians and of responding to non-COVID patients’ healthcare needs, without placing them at risk of contamination. The distant monitoring of the COVID-positive patient’s health status (especially knowing the fact that it may worsen very quickly) cannot exclude the risk of omission by the physician of the deterioration of the patient’s health condition because of the failure to see the patient, confirm the existence / absence of pneumonia via X ray, measure the saturation level and minimize the risk of late hospitalization.

As mentioned in the Standards of Medical Care “Coronavirus Disease (COVID-19),” if a patient contacts the primary care physician, by means of distance communication, and if (s)he has a severe acute disease, the primary care physician shall recommend contacting the emergency care for subsequent hospitalization. Patients who often delay being taken to hospital, regardless of the physician’s recommendations, may accuse the physician of failure to ensure timely hospitalization. Physicians who distantly control COVID-19 patients’ conditions instead of visiting them run additional risks and should still maintain meticulous records to confirm that which took place and to document advice given.

Taking the above into account, it seems worthwhile developing the detailed recommendations concerning the monitoring of COVID-positive patients’ health conditions via the means of electronic communication and regarding the fixation of pieces of advice given by physicians to their patients via distant communication means (e.g., by phone, ZOOM, etc.)

What lessons may be learned from the Ukrainian experience of the introduction of telemedicine and its use in times of the novel coronavirus disease (COVID-19)?

When taking steps towards launching a useful innovation, it is important not to stop on the mere introduction of it but rather to take care of substantiating its further development, with the use of necessary legislative tools. It is also expedient to draw up recommendations concerning the peculiarities of the

\textsuperscript{67} Vide supra, 32.
use of telemedicine tools, in providing medical care in emergency situations, especially to patients with severe conditions who contacted physicians through distant communication means. While providing new opportunities, the use of telemedical tools is also capable of creating additional risks that can be mitigated by reasonable approaches.

CONCLUSION

In Ukraine, the timely introduction of containment measures helped the healthcare system keep the lights on. The coronavirus crisis has revealed the points of weakness and areas requiring development, relevant to health governance and legislative support. A larger, long-term perspective, when designing and implementing institutional and infrastructural changes, is essential as clear from the Ukrainian “SES” and “hospital stock structure optimization” cases. Emergency preparedness is a core element of this perspective.

The well-known notion of due determination and separation of powers, in the sphere of health care, has proven its topicality. The importance of the issue of quality of legislation, including those adopted in times of emergencies, and the fitness and prompt implementation of such legislation, has been exemplified during this pandemic period. The situation around additional payments to healthcare workers, providing care for patients with COVID-19, is a case in point.

The pandemic has attracted the attention and attitudes of the state and local authorities and the public towards the legal statuses of healthcare workers and their levels of “real life” protection.

The innovative tools of telemedicine require proper legislative substantiation and further development.
UNITED
KINGDOM
MAKING THE PUBLIC HEALTH MANDATE WORK: COVID-19 AND THE CHALLENGES REVEALED IN THE UK

Professor Nicola Glover-Thomas*

Abstract: Any mandate to protect the health of the public is inherently moral. It creates a clear obligation for the state to provide the necessary care for the well-being of all members of society. The collective benefit trumps individual choice. Where such a mandate exists, there is also power to do whatever is necessary to achieve the aims of the mandate. The arrival of the COVID-19 pandemic has brought these tensions within public health to the fore. The UK government has acquired unprecedented powers to manage the pandemic under the Coronavirus Act 2020. This paper examines this legislation and evaluates the system failures and successes that have been revealed by the pandemic.

Keywords: COVID-19; UK; Coronavirus Act; Discrimination; Pandemic; Public Health

Introduction

This paper will consider the impact of the COVID-19 crisis in the UK and the legal responses initiated to respond to it. As COVID-19 continues to take hold around the world, the UK government has acquired unprecedented powers in order to manage the pandemic.¹ The COVID-19 outbreak is without doubt an emergency and one which currently remains unquantifiable in terms of its eventual impact. Entire populations are at risk from the disease and some population groups, such as the elderly and those with underlying health conditions, are particularly at risk.

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This paper will consider the initial steps taken by the UK government to slow down the spread of the disease; it will then evaluate the quickly drafted Coronavirus Act 2020 and finish with an evaluation of the system’s failures and successes that have been revealed by the pandemic, in particular, challenges in the protection of healthcare workers, the vulnerabilities of non-hospital based healthcare provision and the potentially discriminatory nature of the legislation and its implementation.

**A National Emergency and the Ethics of Pandemics**

Public health rests on a moral mandate. In the UK, as of the 11th May 2020, there were 220,449 cases with 32,065 deaths. Testing has proven problematic with many keyworkers and those reporting some symptoms of the virus not being tested. The above figures therefore reflect confirmed cases only and it is thought that the number of those suffering from the virus may be significantly higher. The UK is currently struggling with the demands placed upon it to test for the virus, only managing to test around 10,000 people a day. If the UK cannot improve its testing capability, it will be very difficult to identify and contain the virus. It will also be impossible to effectively know when people can return to their normal lives, to go back to work and school and to jump-start the economy once again.

The public health crisis has placed all countries in the challenging position of having to balance the rights of all to protection from risk while also

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4 Data on UK death rates are problematic. The data only include deaths that occurred within hospital and where there was a positive COVID-19 test at the time of death. These figures do not include deaths outside hospital, for example, those that occur in care homes. However, the daily death toll from Covid-19 in care homes began to be issued daily from the 29th April. Interpretation of the figures should also take into account the fact that confirmation of COVID-19 diagnosis, death notification and reporting in central figures can take up to several days and the hospitals providing the data are under significant operational pressure. This approach makes it impossible to compile deaths data on a daily basis using up-to-date figures. See, https://www.england.nhs.uk/statistics/statistical-work-areas/COVID-19-daily-deaths/ (Accessed: 10/05/2020)
maintaining, where possible, individual liberties. The decision to initiate restrictions of movement, other freedoms and ultimately lockdown is one that has not been taken lightly. These freedoms must be balanced with the right to life which is protected by Article 2 of the Convention of Human Rights. This places a positive obligation on the government to take action to protect against infectious diseases. While the right to life is not absolute, it does impose very strong obligations on the state from taking life, except when it is absolutely necessary.

Public health crises highlight stark tensions between liberal values, such as autonomy, liberty and privacy which underpin government rights and responsibilities in the UK and the drive to contain infectious disease. As recognised by Coggon, it is important that we understand what liberty means. It can either be the freedom to be left alone, to do what we please as long as it harms no one else, or the value we place on liberty could require it to be understood to be ‘resting alongside other important values, such as autonomy, community, equity, health, family and friendship, fulfilment and other aspects of flourishing, welfare and well-being.’ To be able to benefit from liberty, there has to be a recognition of the rights of others.

On the 24th March, Boris Johnson, the UK Prime Minister, declared the COVID-19 outbreak a ‘moment of national emergency.’ Measures were introduced to respond vigorously to ‘protect the NHS’s [National Health Service’s] ability to cope - and save more lives.’ Effective lockdown was introduced across the UK with the public only being able to leave their houses for one form of daily exercise and essential shopping, gatherings of more than two people were banned and all shops selling non-essential goods, churches, playgrounds and libraries were also to be closed from that point.

**Initial Efforts to slow Disease Progression**

The lockdown represented a significant turn in the measures introduced to protect against the virus and marked a dramatic escalation in policy. The UK government introduced the *Coronavirus (COVID-19) action plan*, on the 3rd

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March, which outlined what the health and social care system had done to tackle the COVID-19 outbreak and what future steps were to be taken. The action plan outlines several phases of planned action; the contain phase, the delay phase and the research phase.

Containing the disease focuses on catching cases early and tracing all contacts. Public Health England (PHE) has worked with Border Force, port operators and carriers to enhance port health measures. British nationals have been repatriated and health advice and information has been widely disseminated. New regulations were introduced to authorise medical professionals, the police and public health professions with the power to detain and quarantine at risk areas.

When containment failed to halt disease progression, the delay phases were initiated. This focused on individual case identification and isolation continued with sustained emphasis on handwashing and self-containment. The people of the UK were required to socially distance themselves and self-isolate when suspect COVID-19 symptoms developed. Schools were closed.

The UK is currently within the research phase. Containment and delay have not markedly impacted on COVID-19. The Government has intensified its focus on work to understand the virus, to develop diagnostic testing and antibody testing and to develop a vaccine.

The Legal Public Health Response

The Health Protection (Coronavirus) Regulations 2020 were introduced after British citizens were repatriated from Wuhan, China, in February 2020. On arrival, back to the UK, repatriated individuals were expected to enter a 14-day period of isolation at secure locations where they could be quarantined. At the time, there was no legal basis to enforce this period of quarantine and reliance was initially placed on individual consent. Powers under the Public Health (Control of Disease) Act 1984, as amended by the Health and Social Care Act 2008, provide the means to legally authorise required quarantine. The Secretary of State for Health and Social Care invoked a procedure for legislating, in urgent cases, and signed into law the Health Protection (Coronavirus) Regulations 2020. The Regulations applied to two categories of case: those cases involving people whom the Secretary of State or a registered

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public health consultant have reasonable grounds to believe are, or may be, contaminated with Covid-19 provided they also consider that there is a risk that these people might infect or contaminate others (domestic cases); and those cases concerning people who have arrived in England on an aircraft, ship or train, from outside the United Kingdom, and who the Secretary of State or a registered public health consultant has reasonable grounds to believe left an infected area within 14 days immediately preceding their arrival in England (overseas cases). The Health Protection (Coronavirus) Regulations 2020 were repealed by the Coronavirus Act 2020.

While a suite of public health provisions already existed, to cope with a variety of infectious diseases under the Public Health (Control of Disease) Act 1984, COVID-19 and the various repercussions of the disease had not been considered at the time the legislation was drafted. The Coronavirus Act 2020 was introduced to streamline some of the processes in the Public Health (Control of Disease) Act and ensure equivalent powers existed across all four nations of the UK. On 25th March 2020, the 329-page Coronavirus Bill became law, after passing through Parliament in just three days, without opposition from MPs in the House of Commons and without amendment from the House of Lords. The speed and ease in which this Bill passed into law clearly indicates the recognised need to deploy legal powers to curb the virus, a view that generated agreement across all parties in Parliament. The speed of enactment eliminated any opportunity for Parliament to scrutinise the Bill, resulting in significant scope for the legislation to fall short of the normal standards sought when introducing new laws.

The Coronavirus Act 2020 gives considerable powers to the police, immigration officers and public health officials to detain people believed to be potentially infectious and put them in isolation facilities. The legislation allows the government to prohibit and restrict gatherings and public events for the purpose of limiting the spread of COVID-19 and allows people to leave their jobs to volunteer in the NHS to assist with the overwhelming demands being placed upon the service by the virus.

Unlike other legislation, the Coronavirus Act is built around a sunset clause, a clause which provides an explicit expiry date, once it is passed into law. In the UK, sunset clauses are traditionally included in legislation when it is felt that Parliament should have the chance to decide on its merits again after a fixed period. The Coronavirus Act will be in place for an initial two years though this could be shortened or lengthened by regulations, with the government agreeing that Parliament should debate and vote on the legislation
every six months to enable a fluid and reflective statute that can effectively accommodate the evolving landscape of COVID-19.

The purpose of the legislation is to make available the necessary powers needed to respond to the demands placed upon the country, as a consequence of the pandemic. The government has been quick to assure UK people that these powers will only be used if needed and this decision will be judged on the clinical and scientific advice available. A ‘potentially infectious’ person is defined as someone who ‘is, or may be, infected with coronavirus’ or who has been in ‘an infected area within 14 days.’\(^8\) While these powers have the potential to contravene ECHR Article 5 rights to liberty, this right is qualified and public authorities can take proportionate steps to interfere with it to protect public health, including the restriction of movement.\(^9\)

The emergency powers in the Coronavirus Act 2020 sit within five key areas:

(1) Increasing the available health and social care workforce

This includes providing powers to assist with the emergency registration of health professionals (sections 2-5) and social care workers (sections 6 – 7). Powers are provided to facilitate leave and compensation for emergency volunteers (sections 8 - 9), the indemnification of clinical negligence liabilities arising from NHS activities related to the COVID-19 outbreak (sections 11 - 13) and the suspension of pension rules for recently retired healthcare professionals who return to work (sections 45 - 47).

(2) Easing the burden on frontline staff

Provision is made for the rationalisation of procedures for mental health assessments (section 10) and discharge procedures for those leaving acute hospital settings who have social care needs (sections 14 – 17), powers to vary the appointment process for and increase the number of Judicial Commissioners overseeing the Investigatory Powers Act 2016 (section 22) and powers to extend the lifespan of urgent warrants pending judicial approval (section 23), powers allowing vaccines to be administered by a wider range of health professionals in Scotland (section 36), powers to direct the suspension of ports or diversion of arrivals (section 50), powers to expand the availability of video or audio link in court proceedings while making

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\(^8\) See: Coronavirus Act, s. 2(1)).

\(^9\) This legislation is supported by the Public Health (Infectious Disease) Regulations 1988 and has since been amended by the Health and Social Care Act 2008.
provision for public participation (sections 53-57) and flexibility in relation to the number of Treasury Commissioner signatures required for the Treasury to transact business (section 71).

(3) Containing and slowing the virus

Powers are provided to temporarily close, require provision or make directions in relation to educational institutions or registered childcare provider (sections 37-38), powers to test and isolate people who have, or may have, COVID-19 (section 51), powers to prohibit or restrict events and to close premises to prevent, protect against or control the incidence or transmission of COVID-19 or facilitate deployment of medical or emergency personnel and resources (section 52) and powers to postpone the local, mayoral and other elections and recall petitions (sections 59-64).

(4) Managing the deceased with respect and dignity

Powers are also provided for the rationalisation and streamlining of death and still-birth registration, enabling doctors who have not seen the deceased to certify cause of death, without referral to a coroner, and allowing cremations to take place without additional medical practitioner oversight (sections 18-21), the disapplication of the need for coroners to conduct an inquest, with a jury, for deaths where COVID-19 is the suspected cause (sections 30-32), powers for local authorities in relation to the storage, transport and disposal of deceased bodies (section 58).

(5) Supporting people

Support for people can be found in several places within the Coronavirus Act, including: powers to sanction a member of the food industry refusing to comply with voluntary requests for information (sections 25-29); powers in relation to Statutory Sick Pay, including permitting its payment on the first three days of absence from work, and enabling small businesses to reclaim it for COVID-19-related sickness absences (sections 39-44); and the streamlining of procedures around changes to the system of national insurance contributions (sections 72-74).

The legislation seeks to manage the virus. Key to this is the provision of sanctions where unwillingness to conform to public health restrictions occur. The Coronavirus Act provides powers to the police, immigration officers and public health officials to arrest people deemed infectious when they are not
cooperating with restrictions. Where this occurs, people can then be placed in isolation and sent to be tested and where people refuse to be isolated or tested, they can be fined up to £1,000.

**What the Pandemic Reveals: Systems’ Failure, Success or a Bit of Both?**

*COVID-19 and healthcare workers*

COVID-19 has no boundaries and no one is immune from its impact. The pandemic has exposed some significant weakness in the UK system, yet it has also highlighted fundamental strengths in the framework of UK society. Up to a fifth of the UK’s workforce may be made absent by COVID-19, during its peak weeks in the first wave of the pandemic, and any subsequent ones. For healthcare workers, this is likely to be particularly the case over the coming months as the demands placed on the NHS workforce continues to rise. On the 5th April, the Royal College of Physicians published a survey of its fellows and members where respondents were asked whether they were currently taking time off from their normal work schedule or had taken time off recently; if they were able to access testing for COVID-19; and if they were able to access the appropriate personal protective equipment (PPE). There were 2,513 responses, with 1,932 from members in England.10

During the week of the survey, nearly 22% of members were taking time off work because they were ill with suspected COVID-19 or were self-isolating because someone in their household demonstrated COVID-19 symptoms. Only 31% of respondents with symptoms had been able to access testing with a wide geographical variation across the UK. Only 12.5% of respondents said testing was available for members of the household who had symptoms. 75% of respondents also observed other clinical staff with whom they worked had problems accessing testing; and 70% said they knew of problems for non-clinical key staff accessing testing. Only 78% of respondents were able to access the necessary Personal protection equipment (PPE) with two observable problems - supply and recommendations on what to wear and when.

The apparent lack of support and protection of healthcare workers on the COVID-19 frontline in the UK has highlighted a lack of preparedness for such a global public health threat. People across the UK have come together to

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support and recognise the work of these keyworkers, undertaking community-based work to assist with the production of PPE, fund raise for the NHS and deliver essential goods to vulnerable people.

**Care homes and other care provision outside hospital**

Much of the focus was initially placed upon health care provision for COVID-19, within primary healthcare settings. In the early weeks of April 2020, it became clear that the UK had failed to notice the strain in other areas of care provision. Recorded COVID-19 deaths only include deaths that had occurred within hospital. These figures did not include deaths outside hospital, such as those that occur in care homes. Care homes have been particularly hard hit as residents are among the most at risk, due to their age. By the 24th April 2020 in England, just under 5,000 people had died in a care home of COVID-19.11 (ONS, 2020) These data need to be read with caution, as the death toll is based on death certificates which can take time to issue. The concern is that elderly and vulnerable people have been unfairly overlooked during the pandemic, with limited testing taking place and those that care for them not receiving the PPE they need to protect themselves and those they care for.

For those reliant on social care, the Coronavirus Act 2020 temporarily suspends local authorities’ legal duty to meet the care needs of all people who are eligible under the Care Act 2014. A duty to provide care is only placed upon councils where failure to do so could breach a person’s rights under the Convention of Human Rights (ECHR). This has effectively downgraded the level of care and support that councils are required to provide, leaving those who need it with very little. The expectation was that the easing of these duties will only be justifiable when local authority workforces are significantly depleted, as a consequence of the virus and the demand on social care has increased, to a level where it is no longer reasonably practicable for it to comply with its Care Act duties. There are currently little data available regarding the extent to which social care duties have been suspended but the potential impact of this has far-reaching consequences.

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**Efforts to overcome key UK challenges**

Healthcare workers have been at the frontline since the emergence of the virus and it is expected that this will remain the case for some considerable weeks to come. On the 10th April, the UK government set out a UK-wide plan to ensure PPE gets to where it is needed most.12 This plan has three key strands: guidance, distribution and future supply. The plan emphasises the necessity of being clear about who needs to wear PPE and in what clinical situation, according to UK clinical expertise and World Health Organisation (WHO) standards. Behind this is the notion that PPE should not be wasted or stockpiled, causing supply difficulties elsewhere. The plan also sets out how to ensure that those who need PPE can receive it when needed. It sets out a new national supply system. The plan outlines actions that will be taken to ensure enough critical PPE is available and will last the UK through the COVID-19 pandemic.

In an attempt to overcome the significantly inadequate testing provision in the UK, the Department of Health and Social Care has published plans to step up COVID-19 testing.13 (Department of Health and Social Care, 2020) The UK Government’s testing strategy is founded on five pillars, including: boosting swab testing for diagnosis of disease; the creation of a new swab testing capacity; increased focus on antibody tests to assess immunity; improved surveillance to establish the extent to which the virus has affected the global population; and to build a large diagnostics industry that the UK currently does not have.

While the government plans to overcome the shortages in testing capacity and PPE provision, there remains a high level of scepticism. Healthcare professionals and unions are disappointed by the government’s perceived lack of planning. COVID-19 has been a looming crisis since the beginning of the year and, while the extent of the crisis is unprecedented, recognition that it would have an impact on supplies was not apparent. Observing the unfolding

crisis in China, in the early weeks of 2020, arguably should have been sufficient warning. While the government’s plans to rectify this crisis are commendable, there remains a lack of confidence that these challenges will be overcome. The risk is that healthcare workers may decide not to carry out procedures on patients when they do not have the necessary PPE and they may remain at home instead of being where they are needed, because there is no certainty that they are free from the virus or immune because of testing constraints.

Political uncertainty and unrest

The seriousness of the pandemic has been brought into stark focus in the UK with the Prime Minister, Boris Johnson, succumbing to the disease. Boris Johnson tested positive for COVID-19 on the 26th March, = admitted to hospital on the 5th April and then moved to intensive care after his symptoms deteriorated. Prior to intensive care, Boris Johnson continued to lead the country but, with his changing health the question of who would step into his place emerged. Dominic Raab, Foreign Secretary and First Secretary of State, deputised. What these political manoeuvrings have highlighted is a significant gap in the UK’s constitutional arrangements.

While this is now somewhat hypothetical, as Boris Johnson has now recovered, Raab’s position, as deputy Prime Minister was one where he was acting under clear instructions. He did not have the full range of prime ministerial powers. Had this situation lasted for any length of time, the question is whether this ad hoc arrangement would be adequate for the longer term. Unlike the U.S., the U.K. does not have a constitutional arrangement that sets out a deputy who would immediately take over power if the leader is injured or killed. Far-reaching longer-term decisions, such as: how and when lockdown should be relaxed; how to support the economic bounce-back; and how to deal with Brexit, would be beyond the reach of the ad hoc power that was given to Raab. What this position highlights is that the UK does not have the robust arrangements that are needed in the event there is long-term incapacitation of the Prime Minister and doing more to strengthen this should be a post-COVID-19 priority.

As the potential for political uncertainty emerged, with the Prime Minister being afflicted with the disease, the risk of other forms of unrest also emerged, when the restrictions placed upon the UK public increased. The Coronavirus Act 2020 does not contain safeguards for strikes and industrial action which exist in the Civil Contingencies Act 2004 – a law which sets out the powers
the government has in large scale emergencies. This could have significant implications for political protests, protected by the rights to freedom of expression and freedom of assembly. With a general economic decline expected, recent data also support the view that criminal activity will increase. There may be an increase in COVID-19-related fraud. The National Crime Agency have highlighted concerns about the illegal selling of COVID-19 tests. The risk of criminals seeking to capitalise on the COVID-19 pandemic is high, with criminals impersonating experts, organisations and the police, in order to encourage the public to share personal and financial information.

**The potential for discrimination? The impact on existing illness and frailty**

While focus has been placed on COVID-19, understanding it and responding to its threat, questions continue to be raised about the potential for discrimination in the wake of the Coronavirus Act 2020. International human rights law guarantees everyone the right to achieve the highest attainable standard of health and obliges governments to do what they can to achieve this. It is recognised that when there is a serious public health hazard, restrictions may be necessary and legally authorised under the Siracusa Principles. These principles mean that restrictions and limitations on people can be legitimised when a state must take measures to deal with a serious threat to the health of the population. These limitations should be the ‘least restrictive and intrusive as possible...they should not be...arbitrary, unreasonable, or discriminatory.’ There remains debate, in the UK, about whether the Coronavirus Act 2020 contravenes the Siracusa Principles and whether some groups, minorities and individuals are being indirectly discriminated against.

One area of concern relates to the wider health impact of COVID-19 on those people who are already seriously ill. Almost 18,000 people in England with cancer could die because of the impact of the virus on hospitals. Critical treatment may be suspended and people may decide to avoid hospitals.

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Diagnostic testing and urgent referrals, from GPs for cancer tests, have fallen in the pandemic period. Some surgeries and continuing therapies have stalled.

Further concerns have also been raised, in the UK, over the use of the frailty index to determine who should receive the limited acute hospital care in this pandemic. The NHS in England is the first health system in the world that systematically identifies people, aged 65 and over, who are living with moderate and severe frailty using a population-based stratification approach. The frailty index was introduced to identify those most at risk of experiencing adverse events, including hospitalisation, nursing home admittance and death. Using this assessment, early identification can then be used to assist with interventions and targeted support to ensure older people stay safe and well.

The National Institute for Health and Care Excellence (NICE) published revised guidance, on the 30th March, regarding the critical care of COVID-19 patients. The original guidance that was published on the 20th March used a ‘clinical frailty scale’ to assist in the decision-making process which was followed by an immediate legal challenge on the grounds that use of that scale for these purposes did not fully respect the rights of the disabled, particularly healthy adults with autism or learning difficulties and those with stable conditions such as cerebral palsy. The revised guidance now states that the frailty index should not be used ‘in younger people, people with stable long-term disabilities (for example, cerebral palsy), learning disabilities or autism. An individualised assessment is recommended in all cases where the [the frailty scale] is not appropriate.’ 18 Use of the scale, by implication, is encouraged for those who are older and would normally be subject to an assessment under this scale. The concern is that the frailty index may be used as a mechanism to ration resources against those who are deemed frail under the index and may not be provided with intensive support in the event of COVID-19. The British Medical Association (BMA) acknowledged, in its COVID-19 guidance, 19 that rationing might be needed if demand outstripped available supply and goes on to outline a threshold for

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admission to intensive care. The BMA guidance says: ‘...if there is radically reduced capacity to meet all serious health needs, it is both lawful and ethical for a doctor, following appropriate prioritisation policies, to refuse someone potentially life-saving treatment where someone else has a higher priority for the available treatment. These are grave decisions, but the legal principles were established in relation to the allocation of organs for transplantation and have been recently upheld by the Court of Appeal.’ 

In the mental health arena, there are further discrimination concerns as the Coronavirus Act 2020 weakens safeguards for detaining people under the Mental Health Act 1983. Only one doctor is now needed to decide whether a person should be sectioned, where normally there must be two. The Act also allows for the extension and removal of time limits that normally sit within the Mental Health Act 1983. This might lead to some patients being released into the community early without adequate care and support packages in place or they could find themselves detained in hospital for longer than necessary.

**Conclusion**

At the time of writing, the UK has arrived at a point of further change. The lockdown that was initiated in the UK on the 23rd March, will be relaxed, as per the Prime Minister’s statement on the 11th May. While everyone is encouraged to be vigilant and stay at home when they can, some workers in some industries and sectors are now expected to return to work. Schools for some year groups are likely to open at the beginning of June 2020. While COVID-19 cases are reducing in number, the total remains high. Globally, there is concern that some countries that have already relaxed their approach to the pandemic are beginning to see a rise in cases. The concern remains that a second wave will hit in the coming Autumn.

While sombre in mood, it should not be forgotten that more people died in the second wave of the Spanish flu pandemic (1918-20) than in the first. This is thought partly due to a mutated virus, significant troop movement and an unwillingness, by many public health officials worldwide, to introduce strict quarantine because of the impact this would have on the war effort.

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20 Ibid. [3]. See also, R (BA) v The Secretary of State for Health and Social Care [2018] EWCA Civ 2696.

Contextualising these reasons into current pandemic strategies, it seems plausible that a second wave could be equally damaging, particularly if economic concerns dictate the speed at which protective public health steps are dismantled.

The Coronavirus Act 2020 will remain in place until 2022 and will be regularly reviewed. It is expected that it will remain law for the time it is needed. While there are serious concerns about the legislation and its scope, for now it provides necessary clarity and legal authority for actions to be taken in order to protect the public at large.
USA
CORONAVIRUS PANDEMIC - MEDICAL LAW AND ETHICAL ISSUES IN THE UNITED STATES

Thomas Noguchi* and Richard S. Wilbur**

Abstract: This article examines Corona virus (Covid-19) originated in Wuhan, China in late 2019 and appeared in early January in the USA and California. During early March 2020, the virus spread rapidly throughout the USA. According to Governor Andrew Cuomo, the mass infection first spread to Europe and arrived in New York City (NYC), overwhelming healthcare facilities. The probability of California experiencing a similar situation to NYC was greatly diminished by Governor Gavin Newsom’s issuance of the Stay at Home order, issued on March 16, 2020, which encouraged businesses to continue adapting their offices to an online format and workers to work remotely.

Another medical law and ethics issue is the racial hate and discrimination towards the Asian community. Discriminatory remarks such as “Go back to China” to Asians has been overheard.

The Center for Disease Control (CDC) guidance was issued in May 2020 stating, “while some communities will progress sequentially through the reopening phases, there is the possibility of recrudescence in some areas.” “Given the potential for a rebound in the number of cases or level of community transmission, a low threshold for reinstating more stringent mitigation standards will be essential.

A number of lessons can be learned from this event. A pandemic requires national and international coordination, planning and implementation. Until the global infection is eradicated, second waves of infection will likely surge.”

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**Keywords:** Epidemic/Pandemic; Corona Virus Infection; Originated from Wuhan; China; Infection in the USA, Implication to Medical Law and Ethic

**Introduction**

ALooking back at how average Americans learned about corona virus infections arriving in the USA, [TN1][TN2], their attention may not have been fully addressing the oncoming coronavirus in early January 2020, still drawn towards the political turmoil, generated by the upcoming presidential election in November 2020. The Congress was set to move and vote on articles of impeachment against President Donald Trump. Newspaper and media were largely ignoring the coronavirus’ coming to the US until late February or early March 2020. To Americans, the Covid-19 pandemic arose rapidly as the infections initially were identified in most major metropolitan areas by early March 2020.

Early in November and December 2019, coronavirus started in Wuhan, Hubei China. Dr. Wu (1) chronologically documented the first 27 cases and 0 deaths in Wuhan City, Hubei Province, China. On December 8 and 31, 2019[TN3], the center reported to the World Health Organization (WHO) in Wuhan. On January 7, the new virus was identified. The WHO sent out a global Emergency Alert as the infections in China rose to 7,736 cases with 170 deaths. There had been 82 cases with 0 deaths outside of China. By February 20 2020, China had 74,675 cases, 2,121 deaths, with 1,073 cases and 8 deaths outside of China.

During early March, the virus spread rapidly throughout the US and even more so in New York, especially in New York City (NYC). According to Governor Andrew Cuomo, the mass infection first spread to Europe and arrived to NYC. Because of the oncoming pandemic, many scheduled conventions, scientific meetings, national and international events, such as the Summer Olympic Games, were rescheduled or cancelled. The scheduled WAML congress in Toronto Canada for August 2020 also had to be cancelled, the next congress being scheduled in Istanbul in 2021. Schools have been closed and online instruction has been implemented. Graduation ceremonies have been cancelled. Medical appointments shifted from being face-to-face to online telemedical consultations. Despite the initial delay, since the pandemic began in the US, the government has been coordinating research efforts, documenting the virus’ epidemiology and advocating for increased COVID-19 testing, including offering to send a team of Centers for Disease Control (CDC) health experts to China to help contain the outbreak.
On January 8, the CDC issued an official health advisory via its Health Alert Network (HAN) and established an Incident Management Structure to coordinate domestic and international public health actions; on January 17, the CDC noted that person to person spread was not confirmed, but was still a possibility; and on January 20, it activated its Emergency Operation Center (EOC) to further respond to the outbreak in China.

The earliest known US death from COVID-19 occurred, in the State of California, on February 6 in Santa Clara County, a 57-year-old woman who died from complications caused by coronavirus which apparently led to a ruptured heart. This case was only confirmed months later, posthumously from tissue samples taken by the county coroner and sent to the CDC for testing, with the infection estimated to have occurred several weeks earlier, what has now been established as an untraceable community-based spread of COVID-19.

On May 20 2020, the John Hopkins University coronavirus database reported the following numbers of infected and death cases by U.S State:

<table>
<thead>
<tr>
<th>State</th>
<th>Infected</th>
<th>Deaths</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York (state)</td>
<td>356,458</td>
<td>28,724</td>
<td>-</td>
</tr>
<tr>
<td>New Jersey</td>
<td>150,399</td>
<td>10,747</td>
<td>-</td>
</tr>
<tr>
<td>Illinois</td>
<td>100,418</td>
<td>4,525</td>
<td>-</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>88,970</td>
<td>6,066</td>
<td>-</td>
</tr>
<tr>
<td>California</td>
<td>84,057</td>
<td>3,436</td>
<td>-</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>64,412</td>
<td>4,767</td>
<td>-</td>
</tr>
<tr>
<td>Michigan</td>
<td>53,009</td>
<td>5,060</td>
<td>-</td>
</tr>
<tr>
<td>Texas</td>
<td>51,323</td>
<td>28,234</td>
<td>-</td>
</tr>
</tbody>
</table>

Since the coronavirus was initially detected in the US, NYC has been critically impacted with a high volume of Covid-19 cases, overwhelming its health care system. During March 2020, Governor Andrew Cuomo requested federal agency assistance in providing additional hospital beds and personnel. The US military provided support and converted a large convention center into a shelter. US Navy Hospital ships were also sent to ease overcrowding in local hospitals. The USNS Mercy arrived in Los Angeles on March 27, just a few days before her sister ship, USNS Comfort, arrived in NYC. The two
ships were sent to serve as a “relief valve” for local medical facilities battling COVID-19 in hard-hit areas by treating patients suffering from other ailments.

The population of the State of California is the largest within the US states, with 40 million inhabitants. Los Angeles County is the most populated county with 12 million residents. While Los Angeles county remains one of California’s most affected areas with more than 35,000 confirmed cases, it has not seen anywhere near the more than 100,000 cases in New York City, a much more densely populated area.

The first case of Covid-19 in the US state of New York was confirmed on March 1 2020[2]. Quickly thereafter, NYC saw an increasing number of infected and sick patients. Originally, authorities described the epidemic as caused by the virus and the pandemic as “caused by fear” and reassured the public that the situation would be under control given the capabilities of New York’s health care system.

Total # of infected and death cases in NYC:
361,515 confirmed cases
29,141 deaths

Governor Andrew Cuomo of New York eventually issued a Stay at Home order in the State of New York on March 22, but the delay is likely a contributing factor as to why the state has become the US epicenter of the coronavirus outbreak. Cuomo has held a news conference, sometimes for several hours, giving up-to-date information on the experience of dealing with an overwhelming number of Covid-19 cases. Those news conferences, started in mid-March, have continued since. He has answered reporters’ questions free of political influence and without placing blame, thanking the federal government for its assistance. It has been very educational and informative for New York’s citizens.

The probability of California experiencing a similar situation to NYC was greatly diminished by Governor Gavin Newsom’s issuance of the Stay at Home order, which encouraged businesses to continue to adapt their offices to an online format and workers to work remotely. Newsom issued the Stay at Home Order on March 16 2020 to protect the health and well-being of all Californians and to establish consistency across the state in order to slow the spread of Covid-19.

The infection rate in NY state and California differ due to population densities and their approaches to lockdown and timely social distancing.
The executive order, issued March 19 2020, by Gov. Gavin Newsom, ordered all California residents to stay home, except as needed for certain essential activities. There was no end date on the order. Restrictions will be in place “until further notice,” it said. Timely declaration of the Stay at Home order, on March 16, saved California from the epidemic spreading widely. Healthcare systems could easily be overwhelmed with a massive number of patients in hospitals.

The Effect of Social Distancing and Stay At Home Order:

The City of Los Angeles required everyone to wear a mask while going out to fulfill essential work or grocery shopping. Frequent hand washing, with soap or alcohol-based disinfectant, is required. Social distancing entails maintaining a 6 feet (2 meters) distance from one another, to avoid congested gathering.

What Jobs are Considered “Essential”?

Besides the staffing of those businesses allowed to remain open, the order specified the following to be sectors needed to maintain societal operation:

[•] schools,
[•] childcare,
[•] construction (including housing construction).

[•] Grocery stores, farmers markets, food banks, convenience stores, take-out and delivery restaurants, gas stations, pharmacies, laundromats/laundry services, banks

[•] Essential state and local government offices and services, including law enforcement.

What’s Closed?

Dine-in restaurants, bars and nightclubs, entertainment venues, gyms and fitness centers, public events and gatherings, convention centers were shut.

Racial and Socio-economic Issues

Another medical law and ethics issue was the racial hate and discrimination towards the Asian community. Discriminatory remarks such as “Go back to China” to Asians has been overheard.
High alarming rates of infection have been noticed in some of Los Angeles’s richest enclaves, including Bel-Air, Beverly Crest and the Hollywood Hills, all having infection rates over 100 per 100,000 residents, as of April 1. Hancock Park’s rate is over 200. Middle and lower-income areas, such as Huntington Park, South Park and Boyle Heights all had rates under 25 per 100,000.

The impact of COVID-19 on the black community was also a concern. There is a disproportionally larger number of both those infected and those dying in the black community, with 17,000 deaths reported in the black population. Black people make up 13% of the US population but the death rate of those infected was 27%.

Former Surgeon General, Dr. Regina Benjamin, said the black community has a higher rate of hypertension, cardiac disease, obesity and diabetes, all predisposing to a potentially more serious outcome. Black Americans also face more barriers to quality healthcare than do White Americans.

Another factor is the challenge the black community faces in maintaining social distancing, due to more-crowded living arrangements. T.J Jacks, a well-known black pastor and community leader, talked to CNN news, saying that black people cannot stay home and have to work outside. The types of work employing most Black Americans cannot be done remotely via computer, with jobs generally being in construction, farming, sanitation and caregiving, all requiring close contact with people.

The Homeless during the COVID-19 Pandemic

The public has been concerned about homeless people and their encampment and unsightly tents on sidewalks. If living out on the street, there is no way one can maintain hand hygiene and appropriate nourishment. Since there is a large number of unoccupied hotel rooms, in some circumstances, these vulnerable people have been accommodated. (Los Angeles)

CDC Guidelines for Reopening:

This 60-page document, May 2020, was posted on the CDC website without a formal announcement; therein CDC guidance stated, “while some communities will progress sequentially through the reopening phases, there is the possibility of recrudescence in some areas.” “Given the potential for a rebound in the number of cases or level of community transmission, a low threshold for reinstating more stringent mitigation standards will be essential.” Los Angeles, as of May 24, is not ready for reopening.
Conclusion:

This special edition of the WAML Journal on Medical Law and Ethics concerning the coronavirus pandemic is a significant and tremendous effort with special authors from key countries of the world.

So far, the extraordinary spread of the virus on a global scale can be mitigated by social distancing and hygiene. There is no effective therapeutic medication and no vaccine has yet been developed. The pandemic has caused global financial impacts and increased unemployment.

A number of lessons can be learned from this event. A pandemic requires national and international coordination, planning and implementation. Until the global infection is eradicated, second waves of infection will likely surge.

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