

Medicine and Law

World Association for Medical Law

THEME ISSUE

**The Covid-19 Pandemic
A Time Capsule of the First 6 Months
An International Perspective**

Volume

39



Number 2

June 2020

Published by William S. Hein & Co., Inc.
Getzville, New York 2016

International Center for Health, Law and Ethics
University of Haifa, Law Faculty, P.O.Box 6451
Haifa 31063, Israel

ISSN 0723-1393



ISRAEL

LEGAL AND ETHICAL RAMIFICATIONS OF COVID-19 IN ISRAEL

Jonathan Davies¹

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 countries². 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 mentioned³.

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 Declaration⁴ 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-ae173113c796>

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 Declaration⁶.

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

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%3Aaaid%3Aascds%3AUS%3A05eba217-fad8-4c79-89ff-cc9868c92c51>

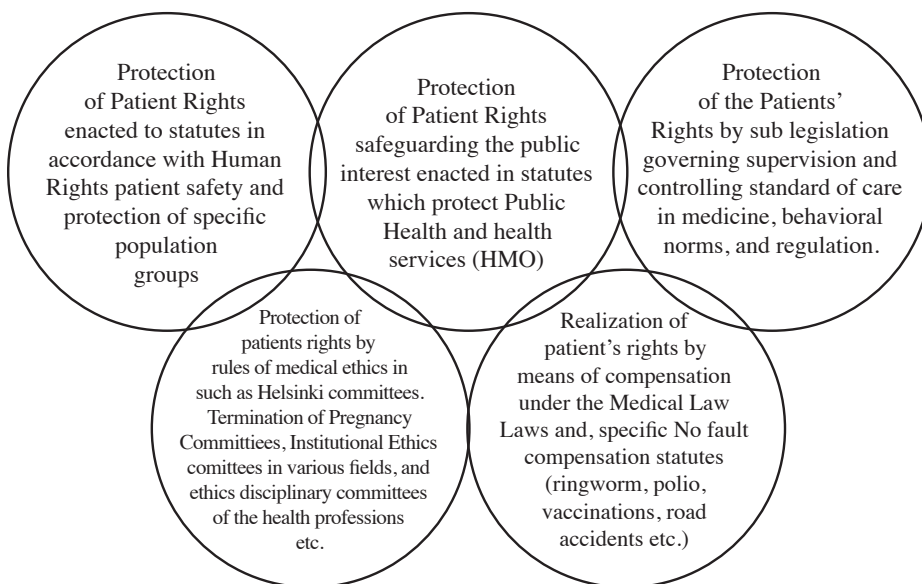
6 <https://www.esahq.org/uploads/media/ESA/Files/Downloads/Resources-PatientSafety-SignedHelsinkiDeclaration/Helsinki%20Declaration%20-%20signed.pdf>

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



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/>

(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 Zoom™, 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.

8 Section 5 of the Patients' 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 individual⁹.

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.

9 <https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:02659468-ff2c-4408-8e08-0455aa0a0dff>

10 Supreme Court of Justice Petition 2435/20 Yedidia Leventhal, Advocate v. The Prime Minister and others (published in Nevo 7/4/2020)

