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Vera Lúcia Raposo Roy G. Beran *Editors* 

# Medical Liability in Asia and Australasia



Vera Lúcia Raposo · Roy G. Beran Editors

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# **Public Health Care Law and Ethics** in Israel



**Jonathan Davies** 

Abstract The Israeli health care system is considered to be of high quality and economically efficient. The Israeli health system provides equal health care services, under budgetary restrictions, to all its citizens. The Israeli decision-making process, regarding public funding of new medical technologies, is fair, transparent and evidence-based, in a way that fulfills the responsibility of the Israeli government, to provide equal health services to its people. This chapter introduces to the readers a brief overview of the Israeli health care system, covering different health issues, such as public health policy, organization of health services, public health and technology, artificial intelligence (AI), healthcare regulation of medical research and clinical trials. It will review legal aspects, such as the relationships between public health, law, human rights and ethics, protection of patient safety in Israel, Balancing between public health issues and individuals rights. In light of the pandemic that struck the world, it reviews the impact and ramifications of Covid-19 on health system and human rights in Israel.

### 1 Introduction

Public health law in Israel is a dynamic field that covers many issues with science, medicine and law converge. The main issue in public health law and ethics is to protect public interests, in light of human rights principals that reflect the essence of the state of Israel, being a Jewish democracy. The topics of public health law and ethics, in Israel, range from protecting the rights of the individual to public interests by large. Public health law protects the population, such as patients, minors,

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handicapped and elderly. Private health law deals with issues, such of pregnancy and childbirth, termination of pregnancy, sperm donation, surrogacy, experiments on humans, biotechnology and law, organ transplants and organ trade, curing diseases, by means of cloning, genes implantation, protection of genetic information and the dying patient. These issues constitute public health policies of the health system, in Israel, and reflect its definition as a welfare state.

Legal medicine in Israel is set by legislation and by court ruling and traverses the boundaries of civil law, criminal law, family law, labor laws, administrative law and evidence law. Public health law and patient's rights derive from legislation and court ruling. The accepted causes of action, in legal medicine, are medical malpractice, wrongful life and informed consent, governed by principles of patient right to autonomy, that is considered as a constitutional right.

The main function of the courts, in interpreting public health law and ethics, is to find an appropriate balance between public and individual interests and applying the appropriate health policy between the many considerations of the various disciplines involved.

Since the outbreak of Covid-19, there has been a sharp transition in the balancing point, on the scale of protecting human rights from an individual to public interests. The world, including Israel, is in a constant battle to recover from the pandemic, trying to return to normal life. Israel experienced a sharp transition, from a normal functioning health system, under a liberal democratic system of government and the civil freedoms, to a national state of emergency. A series of orders and emergency regulations, introduced within months, including lockdown and quarantine, road closures, mobile surveillance by the security services and social distancing have changed the order of life and the economy of Israel.

The chase, to prevent a spread of the pandemic, was drastic, constituting an infringement of basic constitutional rights, enshrined in basic laws, such as freedom of movement, the right to property, freedom of occupation, the right to privacy, freedom of information, freedom of religion and individual human rights.

This chapter provides a brief overview of the Israeli health care system, covering both health and legal aspects: doctor and patient relationship; and patient's rights, through the main causes of action in Israel's legal system.

### 2 The Health Care System in Israel

The Israeli health care system is considered high quality and economically efficient. Health indicators are comparable with those of developed countries. Life expectancy for males is 81 and for females 84 years and infant mortality is 3.6 per 1000 live births. Inequalities, in health indicators, exist with lower scores for those living in the periphery and for minorities. The Israeli health care system is considered one of the advanced in the OECD countries in the world.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> http://www.oecd.org/israel/.

According to The National Health Insurance Law,<sup>2</sup> every Israeli citizen is entitled to an extensive basket of health services, funded by the government, in return for a health tax, constituting 4.8% of the gross salary (up to a certain ceiling). Citizens earning a minimal income taxed only 3.1% and citizens on welfare or retirees are exempt.

**Public Health Policy**: Since 1995, Israel operates a compulsory National Health Insurance (NHI) scheme, which supplies all Israeli citizens with a wide benefits package. There is co-payment for ambulatory services and drugs. Despite the good quality public system, private health expenditure is increasing. There are indications that some of the poor are forfeiting medical treatment, mostly medicines.

The NHI act, from 1995, provides all citizens, with no discrimination, a basic basket of compulsory medical services. Services provided by four health care providers (HMO) that are state budgeted. These agencies can provide private insurances of all kinds. The health basket is a list of drugs and medical services and technologies to which all citizens are entitled. A national committee that presents public and private views on medical, economical and legal interests meets annually to expand or decrease the health basket.

The committee plays a major bioethical role in deciding which new drugs or medical technologies are to be introduced and which patient is entitled to these free benefits.

In addition to the NHI that provides basic medical services, the HMOs and the insurance companies may offer private insurances and provide services beyond the basic basket. More than half the population holds private insurance.

This situation creates a significant gap and disparity between patients who need the services covered by the NHI and patients who seek the services of private practices. This dichotomy also creates a difference in the quality of the medical services. A substantial number of health providers operate in private practice and dedicate most of their time there, in addition to their work in public healthcare.

Time and resource constraints, especially in the public healthcare system, affect the relationship between the doctor and the patient. Investing time and resources, in private medicine, raises the cost of the treatment and comes at the expense of the quality of the treatment in the public healthcare system, thus lowering the standard of care for those patients or decreasing the number of patients who receive care.

Courts are often requested to rule against health funds, in cases of discrimination, which, in some extreme cases, may mean a death sentence, in cases of patients who cannot afford the lifesaving drugs, which are excluded from the basket. Courts have wide discretion in interpreting the NHI Act based on moral, equality and human rights values. HMO funds will finance necessary procedures abroad that are not executed in Israel, due to lack of experience.

<sup>&</sup>lt;sup>2</sup> The statute enacted on January 1 1995.

**Organization of Health Services**: The government plays a major role in the health market, as it budgets the system (95%). These include as: regulator; has direct financial and operational responsibility of medical services, such as geriatrics and psychiatry; owner and operator of 40% of hospital beds; and insurer of all medical services, through the insurance scheme for elementary and professional liability of all their activities.

The four health plans funds supply the actual medical services to the public, owned or bought facilities and personnel.

**Workforce**: There are 3.4 physicians per 1000 people. This ratio is declining, due to an inadequate increase in intake in the medical schools. Corrective measures, to train doctors in peripheral medical centers, will become effective in about 10 years. The system also suffers from a shortage of physicians, in specific specialties, and of nurses in relation to the situation in average of the Organization for Economic Cooperation and Development (OECD) countries.<sup>3</sup> During the second wave of Covid 19 Health, the system suffered a substantial shortage of physicians, especially in intensive care units in peripheral medical centers that were understaffed.

### 3 Legislation

Israel's legal system is based on the common law. Israel has no constitution. The Israeli parliament (Knesset) has enacted several basic laws, serving as a kind of a constitution based on a common law.

The right to healthcare is recognized as a fundamental right in the Israeli legal system and consists of many rights, scattered among many legislations. Among the rights are included: the right of privacy; right of dignity; right of equality; right to proper medical care; right of information; right for access to medical care; and right to confidentiality.

These rights, regulated by laws, and recognized as having superior status and considered as basic laws that protect human rights. The main basic law that the Knesset has enacted is the **Human Dignity and Liberty Basic law-1992**, which regulates the basic rights for dignity and privacy of an individual in society.

Other legislation protects specific groups in society. **Patient's Rights Law**-1996 regulates the rights of the patient and general physician—patient's relations, **Freedom of Information Law**-1998, allows transparency of information and acknowledges the right of every person to information subject to certain restrictions, **Protection of Privacy Law**-1981 protects the person's right of privacy in the society. **National Health Insurance Law**-1995 regulates the rights of the residents for health insurance and a minimum medical services basket, via the Health Maintenance Organization

<sup>&</sup>lt;sup>3</sup> Scheffer (2012), the Global Shortage of Health Workers and Pay for Performance. Improving Health and Health care, who is responsible!? Who is Accountable, Israel National Institute for health policy 2012, pp 87–96.

(HMO) of which (s) he is a member. The Knesset enacted the **Dying Patient Law**-2005, regulating euthanasia and the right of the terminally ill to die with dignity. In 2007, the Ministry of Health established regulations of the dying patient.

National Health Insurance Law is one the most dynamic laws and reflects the tension between the declared protection of the Health Insurance Law of individual rights in general and the right to healthcare, in particular, and administering healthcare economics, within the reality of limited resources.

Since the ratification of the **National Health Insurance Law**, by the Knesset, about 700 changes in legislation, of different and diverse subjects (most of them within the National Healthcare Law and some through the Economic Arrangements Law), were brought before the Knesset for ratification. The majority of the issues, which require frequent legislation changes, are HMO registration policy, HMO administration, coverage of medical services basket, funding of medical services basket, health tax, resource distribution, among the different HMOs and others. Additional laws regulate the rights of underprivileged groups in the society, such as handicapped or minors. The **Equal Rights of Persons with Disabilities Law**-1998 regulates the right of handicapped in the society and the **Legal Capacity and Guardianship Law**-1962 regulates the rights of wards and minors. The **Mentally Ill Law**-1991 regulates the rights of the mentally ill. In 2008, the Knesset enacted the **Organ Transplantation Law** and the law for determining brain-respiratory death. Several committees are continuing to discuss the current health laws and potential new laws (such as the Medical Experimentation Law; Egg Donation Law).

Israeli legislation has explicitly provided a no fault compensation (Absolute liability) in four cases of damages, caused by specific medical treatments: damages to road accident injuries subject to proof of compulsory insurance and driving license; damages caused by vaccination; damages caused by radiation therapy for ringworm of the scalp (Tinea Capitis).and damages caused to patients who suffer polio. These compulsory no fault damages, covered by the State and private insurance (according to the **Road Accident Compensation Act**), notwithstanding causation or negligence. Apart from these, the overall tort regime, in medical law, is subject to proof of negligence and causation.

**Financing**: Israel spends about US \$2,200 per capita per year on health care, 7.8% of its GDP, of which about 57% is public, covering mostly the statutory benefits package, and 43% private. The public resources originate from a dedicated health tax and other general taxes. The pooled public resources distributed between four HMO, via a capitation mechanism adjusted to age.

The committee for the national health basket, restricted by the budgetary limit dictated by the government each year and the budget, usually stands at 0.6 to 0.8% of the total cost of the Health Insurance Law.<sup>4</sup> The estimate of the total cost of technologies, submitted to the TAW for consideration in the 2020 Basket, is approximately 3 billion NIS.<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> Figures for the 2020 Basket were 500 million NIS (\$150 million), with the financing of the Health Insurance Law currently standing at approximately 60 billion NIS (\$17.5 billion).

 $<sup>^{5}</sup>$  \$1 = NIS 3.5.

Israel's poverty rate and income inequality measures remain high, relative to most other OECD countries, despite continuing decline in recent years. The multi-ethnic fabric of Israel is culturally enriching in many ways, yet also poses challenges to equal access to care and implementation of culturally appropriate health services and programs.

The government, through services in the community and medical institutions, finances medical services provided by HMOs. The state owns 40% of the hospitals, the HMOs own approximately 40% of the medical institutions and the rest are privately owned hospitals and clinics.

Statutorily permissible supplementary insurance plan have been sold by the health plans to 80% of the population. A citizen is entitled to join with no underwriting and low community premium rates. About 50% of the population purchases supplementary insurance programs.

Due to Covid-19, it is expected that Gross National Product (GNP) of Israel will fall by 6% approximately.

### 4 Public Health and Technology in Israel

In an era, when new techniques and technologies are constantly evolving, there is growing public demand for prevention and early detection of disease, along with zero tolerance for misdiagnosis. This climate, enhanced by medical malpractice claims, efforts of industry, to promote use of new technologies and a tendency of the media to be overly involved in the formation of public opinion health is important.

Israel is big in health data, is a hub for digital health innovation, implementation and evaluation and is considered amongst the world leaders in the field of medical devices development. According to the recently released Start-Up Nation Central report, the number of digital health companies, operating in Israel, reached 580 in 2019 (more than doubling since 2011), and, in the last year, Israeli digital health start-ups raised \$662 million. Such achievements earned Israel the rank of the world's sixth most innovative country by the Bloomberg Innovation Index in 2019.<sup>6</sup>

Israel is into "big data". The National Health Insurance Law provides all Israeli citizens with comprehensive health and medical care, through one of the country's four HMOs. Virtually all the accumulated medical data, on all citizens is digitized and access to the accumulated and digitized data provides a fertile landscape for medical research. Last year, the government approved a 1 billion-NIS (\$276 million) investment into digital health, focusing primarily on exploiting the country's digital electronic health records (her) system and medical data repositories. These initiatives offer great promise for advancing medical science and practice, while generating data-security, together with legal and ethical challenges, which are currently the subject of draft guidelines of the Ministry of Health.

<sup>&</sup>lt;sup>6</sup> https://www.bloomberg.com/news/articles/2020-01-18/germany-breaks-korea-s-six-year-streak-as-most-innovative-nation.

Israel has already met targets for maternal, neonatal and under-5 mortality, largely thanks to universal health coverage and free education. Despite these remarkable achievements, maternal and child health disparities persist, particularly between Jews and Arabs, and between center and periphery, and Israel struggles with a very high level of child-poverty.

The Ministry of Health has established a Department of Technology Assessment and appointed a national Basket Committee that would make evidence-based decisions about the inclusion of new technologies in the public basket of services.

### Artificial Intelligence (AI), Healthcare and Human Rights

Recent advances in healthcare outcomes are attributed to improvements in the three pillars of healthcare: prevention; diagnosis; and treatment. Artificial intelligence (AI) has applications across all three pillars but its greatest impact has been on improving the accuracy of medical diagnosis, changing the traditional clinical diagnosis.

Clinicians use a wide range of approaches, in order to diagnose disease. The simplest and most widespread is to identify the patient's symptoms and correlate them to conditions or diseases that are characterized by the same pattern of symptoms. The same basic approach applies in interpreting the results of diagnostic tests: a radiologist reviewing magnetic resonance imagining (MRI) or a pathologist analyzing a biopsy sample compare what they are seeing to what they have learned, in order to make a diagnosis.

One of the most advanced AI collaboration, medical research community and high technology, is currently taking place in Israel. This investigator-initiated, prospective, randomized, two-arm, multiple users, interventional, clinical study is aimed to explore the performance and usability of the EVA device (Google LLC). The EVA device is a novel, AI based, automated, real-time lesion detection software, intended to assist adenoma detection in colonoscopy, by highlighting the suspected lesion on the secondary EVA screen. The EVA system is composed of a software, installed on a dedicated personal computer (PC) and monitor, assembled on a portable cart or mounted on the wall. The EVA computer, connected to the colonoscopy, receives the real-time video. The EVA AI algorithm uses a neural network, trained over 7,500 colonoscopies, tested on over 10,000 patients, and is currently in the process of the ethical committee approval.

In the last several years, systems based on machine learning or deep learning began developing to automate the diagnosis of disease, across a range of medical specialties. Few of these technologies are currently in use, though early results suggest that they have great promise in improving the accuracy of medical diagnosis. The promise of AI, to improve our lives, is enormous. AI-based systems are already outperforming medical specialists in diagnosing certain diseases. AI also has downsides. Among these is that AI systems depend on the generation, collection, storage, analysis and use of vast quantities of data with corresponding impacts on the right to privacy. AI techniques are used to discover some of our most intimate secrets by drawing profound correlations out of seemingly innocuous bits of data. AI can easily perpetuate existing patterns of bias and discrimination, since the most common way to

deploy these systems is to "train" them to replicate the outcomes achieved by human decision-makers.

### 5 Regulation of Medical Research and Clinical Trials

The scientific research, 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.

Wide ranges of medical experiments in Israel are conducted in various fields: pharmaceuticals medical devices; products containing cells and tissues; and epidemiology of diseases. For the last thirty years, primary care in Israel has been computerized. An enormous wealth of data is stored on the mainframe computers of the four HMOs that insure all of Israel's population.

The health ministry closely supervises most research approved by each institution's committee. The local ethical committee must include, amongst others, a head of department of Internal Medicine and a representative of the public. All genetic research needs the additional approval of the Higher Helsinki Committee for Medical Trials in Humans, based in the Ministry of Health.

Ethical committees are required to make their decisions based on transparency, safety and effectiveness of medical care, in accordance with the Declaration of Helsinki, and in accordance with the Genetic Information Act, 2000, Genetic Intervention Prohibition Law (Human cloning and genetic modification in reproductive cells), 1999 and in accordance with the procedure of human experiments.

The higher Helsinki Committee examines and approves proposals for all human studies in Israel concerning the genetic system of humans, research related to fertilization, for studies conducted by Ministry of Health staff and any other research, at the request of the Director General of the Health Ministry.

According to the Pharmacists (Preparations) Regulations, drugs are registered in the State Register of Medicines only after safety, efficacy and quality have been proven. The decisions, to register any drug, is made after information is submitted and thoroughly 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 pandemic illness may be 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, 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. These examples reflect an infringement of ethical principles, by making a shortcut in the name of public interests.

In October 2020, the Ministry of Health allowed, for the first time, researchers in clinical trials to accept informed consent of participants by digital means and distance conferencing, subject to specific restrictions of transparency and protection of privacy.<sup>7</sup>

## 6 The Relationships Between Public Health, Law, and Ethics

The Public Health Ordinance is an ordinance, enacted in 1940 by the British Mandate authorities, which regulates the activities of the health system in a large scope of areas: public health; births and death registry; water and milk sanitation; burial arrangements; licensing of medical institutions; health; and the environment. By virtue of this ordinance, regulations, such as: medical experiments on humans; in vitro fertilization; and disease control, including infectious diseases, are regulated according to the public health ordinance. Regulations, enacted to fight the Covid 19 pandemic, were enacted under this statute.

The National Health Insurance Act has shaped the relationship between citizens and basic human rights for medical care.

The origins of the relationship, between public health issues and human rights, influenced by the 1964 Helsinki Declaration, was considered 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 -1980 and, since then, procedures have been published focusing upon management of general research and particularly in the framework of the Ethics Committees of the Ministry of Health, hospitals, medical institutions and the HMO funds.

There are various models to describe the complex legal relationship between a health provider and the patient.<sup>10</sup> Each of the models has balanced the obligations to inform and the patient's right to receive the substantial information. The balance point has changed over the years: At first, the paternalistic presupposition that the

<sup>&</sup>lt;sup>7</sup> Ministry of Health in Israel. Guidelines for informed consent in Clinical trials via digital instruments. October 2020.

<sup>&</sup>lt;sup>8</sup> 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.

<sup>&</sup>lt;sup>9</sup> 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%3Ascds%3AUS%3A05eba217-fad8-4c79-89ff-cc9868 c92c51.

<sup>&</sup>lt;sup>10</sup> Nili Krakow—Eyal, Informed Consent Doctrine, Hapraklit, Volume 49, 181, 171–218.

authority to make decisions, in the matter of a patient given solely to the doctor (Confidential Model) was prevalent. Later, the patient's right to agree or refuse the treatment, based on information regarding the nature of the treatment (Consensual Model), emerged. An additional development was made when broad interpretation was given to the patient as a right to autonomy. The Supreme Court of Israel decided that a patient has not only the right, to agree or refuse treatment, but also the right to receive additional information regarding the suggested treatment, allowing him/her to make an informed decision. According to this model (Autonomy Model, Participatory Model) "the patient has a material and active role in the decision making process: he must examine the information he was given, weigh the advantages of the suggested treatment and its disadvantages, examine the advantages and disadvantages of alternate treatments and decide, based on information and values, most suitable medical treatment for him". The health provider has the duty to inform the patient, in addition to the information regarding the nature of the suggested treatment.

In the **Kadosh** case, the Supreme Court in Israel adopted the American approach known as "*The Shared Decision Making Model*". This model, perceives the doctor and the patient as two parties who share making the decisions, which will be best for the patient. The patient him/herself eventually made the final decision, regarding the appropriate treatment. The doctor is obligated to take part in this process and provide all material information needed for the patient decision, as stated in the Matthias ruling<sup>12</sup>:

There are two approaches, in Israel's Supreme Court, regarding the question of which test applied for examining the scope of the duty of disclosure, on the part of the doctor to his/her patient. The opinion of the majority, expressed in the verdict of Justice Rivlin, in the **Kadosh Case**, adopted the reasonable expectation test. According to the approach of Justice Amit in the **Kadosh Case**, the preferred test should be the involved patient in the eyes of the reasonable doctor. It is predicted that Justice Amit school of thought will prevail.

### Protection of Patient safety in Israel

A large number of legislative enactments governs human rights. Protecting public and individual interests. Basic Law: Human Dignity and Freedom was enacted in 1992 with a constitutional effect on basic rights, such as the right to privacy, the right to informed consent, property and intellectual property rights, freedom of movement, freedom of speech, the right to access health services and prohibition of discrimination. Prior to these statutes, protection of human rights was recognized in universal conventions, such as the Helsinki Declaration. <sup>13</sup>

Public health law is engaged on private and public levels.

• The right to access medical service in Israel, public health, and national insurance.

<sup>&</sup>lt;sup>11</sup> Judge Rivlin in HCJ 1303/09 Kadosh v. Bikur Holim Hospital (2012).

<sup>&</sup>lt;sup>12</sup> Matthies v. Masromonaco, 160 N.J. 26, 36, 733 A.2d 456, 461 (N.J. Sup. Ct. 1999).

<sup>&</sup>lt;sup>13</sup> https://www.esahq.org/uploads/media/ESA/Files/Downloads/Resources-PatientSafetySigne dHelsinkiDeclaration/Helsinki%20Declaration%20-%20signed.pdf.

- The right to medical information entered in the computerized medical records, remote medicine (telemedicine), medical confidentiality and 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

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

- (1) First circle deals with patient rights, designed to protect individual rights of specific groups, such as patients, mental illness (Treatment of Mental Patients Law) the elderly, children, handicapped and other disabled people (Equal Rights for Persons with Disabilities Law), employees (Sick Leave Law) soldiers (Compensation and Rehabilitation of the Disabled Law) and insured persons (Insurance Contract Law).
- (2) The second circle comprises various statutory enactments governing protection of the public interest, such as the Public Health Ordinance (1940) and National Health Insurance Law-1994. Numerous orders and regulations were enacted to protect public interests and balance between public interests and protection of rights of the individual.

(3) The third circle reflects legislation and regulations that supervise standards of care, ethical and behavioral norms, regulation that sets the standard of conduct (Director General's Circulars), the institution of the Ombudsman (Public Complaints Commissioner in the Ministry of Health), Disciplinary and Quasi-Judicial Tribunals.

- (4) The fourth circle expresses the protection of the rights of patients, by means of a series of rules of medical ethics in various fields, such as Helsinki Committees (governing the rules of ethics in relation to scientific and medical research), termination of pregnancy committees, institutional ethics committees in various fields and ethics disciplinary committees of the health professions.
- (5) The fifth circle reflects statutes of no fault compensation acts for disabled individuals that suffer neurological disability, due to ringworm, polio, vaccinations and victims of road accidents. Beyond the right to social benefits that derive from the National Insurance [New Version] Law 5755-1995 and entitles any citizen who suffers substantial disability and compensation to any employee who is injured at work.

The above circles derive their authority from the various legislative enactments and laws on the constitutional hierarchy ladder. In case of a conflict, between public and private matters, the courts balance between such rights with proportionality and in accordance with the purpose of the statute.

### Institutional liability in personal Injury and Tort Law

The boundaries of liability in Public Health Law are sensitive to social, cultural, religious, and technological influences and to the tendency courts play an active role in widening tort liability at large and liability in health law in particular. Many of the medical malpractice cases, dealt by Israeli courts, are medical malpractice cases filed against the State and other various health providers, through the principle of vicarious liability. Tort law and medical malpractice claims serve as a tool for reducing a variety of harms to the population's health.

The goals of tort law, although imperfectly achieved, are frequently consistent with public health objectives. The tort system aims to hold individuals and state accountable for their dangerous activities compensate those who are harmed, deter unreasonably hazardous conduct, encourage innovation in product design and labeling and reduce the risk of injury or disease. Civil litigation can provide potent incentives for people and manufacturers to engage in safer, more socially conscious behavior.

Tort law can be an effective method of advancing the public's health but, like any form of regulation, has its limits. The tort system imposes economic costs and personal burdens are individuals and businesses.

The Supreme Court has considered shifting the pendulum, from protection of human rights of individual to public interests, thus reducing institutional liability of the government.<sup>14</sup> It is to be assumed that case law, post Covid, will follow this trend.

<sup>&</sup>lt;sup>14</sup> Zandberg (2013).

# 7 Balancing Between Public Health Issues and Individuals Rights

Public health strives for maximizing benefits for the highest number of people, while protecting human rights. Restrictions on individual rights are justified for two reasons: for the benefit of the individual; or the benefit of the community.

The common example is involuntary admissions and hospitalizations of mentally ill patients, those present medico legal, moral, social and mostly bioethical dilemmas for the western legal systems. Those are mostly due to the necessity to choose between conflicting principles of deprivation of personal freedom and autonomy of the mental patients vis-a-vis the necessity to protect the safety of society.

Autonomy and the freedom to move freely, at one's choice, is a cornerstone in Israeli legal system. A person may suffer a major medical crisis, such as stroke or myocardial infarct, but retains full choice to refuse to be admitted to the hospital, even when the alternative is a serious jeopardy to his/her life. When a psychotic person expresses suicidal thoughts or threatens to harm him/herself or others and refuses to be treated, then (s)he can be involuntarily admitted and hospitalized in a psychiatric secured ward, losing the liberty to leave and move around at his/her free will. This involuntary admittance, is practiced when such patient has assaulted already or has tried to harm him/herself in the past. When involuntarily admitted, such patient(s) can be enforced with medications, against his/her will with no consent to such treatment, contrary to the basic patients' rights statute requiring patient's consent to every medical treatment, is required.

The legal justification for such deprivation of freedom is clear—safeguarding the safety of public interests. The moral or ethical question remains, but these decreased substantially during the Covid 19 crises.

A series of orders and emergency regulations, introduced within months, including lockdown and quarantine, barriers and road closures, mobile surveillance by the security services and social distancing changed the order of life and the delicate balance between protecting public interests and individual interests.

The chase, to prevent a spread of the pandemic, was drastic; constituting an infringement of basic constitutional rights enshrined in basic laws, such as freedom of movement, the right to property, freedom of occupation, the right to privacy, freedom of information, freedom of religion and individual human rights.

Coping with the outcome of the Covid-19 pandemic in Israel

Since the Covid-19 outbreak, the State of Israel has been coping with 3 waves of lockdowns in which over 1,000,000 citizens caught the virus and over 7500 died of Covid 19 or its complications. The government handled the pandemic by closing the boarders, shutting down businesses, forbidding any form of gathering, such as sporting events, weddings, cultural events (theater and cinema), communal parties, restaurants, hotels and a complete shutdown of tourism. Universities and schools moved to distance learning until the pandemic is over. For the first time, since the

establishment of the State of Israel, as a democratic state government, declared a state of emergency.

From a medical prospective, little was known about Covid 19 and, very soon after the breakout, health providers realized that serious risk factors included medical background, diabetes, obesity and overweight. The prognosis of Covid is vague but early reports show that post Covid long term damages are wide spread and patients report heart and renal failure, hearing and neurological damages and psychiatric outcomes.

Soon after the outbreak, lockdown was forced upon citizens, by means of emergency regulations and orders, restricting the freedom of the individual and constitutes an infringement of basic human rights, such as the right to privacy, freedom of movement, freedom of religion and the right to protest. Despite the declaration to return to normality, the government has not withdrawn the state of emergency, with the support of the Supreme Court. It has left in place the emergency orders that are an infringement of the right to privacy. The Supreme Court of Justice has approved the denial of sacred human rights if the infringement occurs within the framework of principal legislation.

\*\*\*Another characteristic of the pandemic, in Israel, was public dispute, between politicians and public health experts, about how to handle the crises. The main fear of the government was that the health system would collapse justifying the extreme enactments that challenged the Ministry of Health's directives to the public. Another issue was the political state that Israel faced, at the time of the outbreak. The coalition formed was an emergency one and large government that was political based rather than evidence based. This dispute added to the uncertainty and distrust of the government. Covid-19 managed, for the first time in modern history, to infringe the absolute trust citizens had in the political regime and health system but, at the same time, health providers were praised as heroes of the time.

### Informed consent in the age of Covid

The Patient's Rights Act changed the balance of the doctor-patient relationship and created the doctor's statutory duty of disclosure to the patient, by means of the cause of action for informed consent. In the past, informed consent was handled within the cause of action of negligence tort or battery but since the Patient Right's Law of 1996, the duty to receive informed consent was considered part of the right for autonomy of the patient, protected by law.

The meaning of informed consent is that health providers hold a duty to disclose information to the patient necessitating his/her consent and understanding of the information. In order for the patient to give genuine consent to the suggested treatment, health providers need to supply material information about the diagnosis, alternative treatments and prognosis. Failure to disclose pertinent information, regarding the treatment, undermines the consent given for treatment.

The requirement for "informed consent" incorporates two main elements: the one, embodied by the word "informed", relates to the duty of disclosing information to the patient; the second element, embodied by the word "consent", relates to the patient's free will decision regarding the treatment he needs as part of the **right to autonomy**.

Principles of Informed consent, in post Covid age are challenging. Because little is known about the illness, there remains uncertainty regarding the side effects of the Covid-19. Medical publications show that the prognosis of Covid 19 is uncertain and many symptoms can appear even after full recovery.

Doctors are treating the disease with conflicting information, about its ramification and unknown prognosis, which effects, not only adults but also children. Based on this assumption, the rights of the patient to which we have 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, no longer constitute cause of action.

### Informed consent and the future vaccination for Covid-19

There were calls for special attention, to apply mandatory vaccination, in order to benefit society, including those who refuse to be vaccinate. In some states, vaccination is mandatory with only few exceptions (medical or religious). In others, the law mandates that parents receive educational information re benefits of vaccinations, to the child' family and society, and still other states use pinpointed actions, such as expelling unvaccinated children from school or restricting unvaccinated individuals from visiting public areas.

During 2019, Israel experienced a Measles vaccination crisis, while children, of ultra-religious citizens, were infected with measles, after their parents refused to vaccinate their children. This case demonstrates bioethical questions as to the scope of intervention in imposing on parents to vaccinate their children in order to protect the society.

In extreme situations, such as Covid 19, there may be a need to protect public interests that include the health of an individual that refuses treatment; even by overriding individual/parental autonomy. Many countries have mandatory vaccination. These laws curtail individual autonomy, in order to protect society from infectious diseases, because unvaccinated individuals pose risk to the community—including vaccinated individuals (since vaccines are not 100% efficacious). Scientific evidence can exemplify the need for overriding individual autonomy. A divergence, between individual and community benefits, may also exist when there are ideological beliefs incongruent with vaccination or individuals are unaware of or do not accept available scientific evidence.

When the state curtails individual freedoms, for the benefit of society's interests, it should address several issues, including the magnitude of the individual and community risk, the strength of the individual's conviction, wider and long-term consequences of restricting individual autonomy, effective risk communication, best available scientific evidence and transparency of the decision making process. The global chase for vaccination in the battle against Covid 19 is already razing questions as to what will be the attitude of society to sectors and individuals who refuse to receive vaccination under the right to refuse treatment. The right to refuse treatment is part of the right of autonomy that allows individuals to decide on their body.

What if the individual right to autonomy clashes with public interests like the right to Health?

In the post Covid age, the answer is that public interests will prevail. In pre Covid times, when a constitutional right was infringed, the court examined the proportionality of the infringement, striking a balance between the competing interests (the public interest v. personal interest), and, as far as the infringement is disproportionate, the decision will favor the individual.

The Impact of Covid -19 on Health system and Human Rights

Covid 19 has tremendous impact on all avenues of life. The pandemic followed by economic, social and political crises that its implication are too early to forecast.

The traditional players, participating in health care management, are health providers and medical professionals, such as clinicians and public health practitioners, each of whom has his/her own approach to the subject. Other professionals have played key roles in the determination of standards of care. The decision makers, in public policy, are not only health professionals but also public officials, economists, social scientists, politicians, the media and lawyers. The interests of the public, in health care policy, has increased considerably. The questions that have arisen concern the process by which the different disciplines interact. During the Covid 19 crises, politians took over from the professional's responsibility and made the final decisions.

Infringement of patients' rights, in view of the changing swing of the pendulum, from a liberal approach back to a paternalistic approach, emphasizes the shift of the balance. The decrease of the status, of the individual's right to autonomy, will influence the courts discretion, which will be prepared to sacrifice individual rights, for the benefit of the public interest.

In normal times these methods would be dismissed as patently illegitimate, now they are retrogressive *Vis a Vis* the right to life and physical perfection.<sup>15</sup>

This shift has, in the state attitude, caused uncertainty towards the future. In handling Covid crises, especially when decisions are made by politicians, rather than professionals. Will politicians will be accountable to their decisions?

The rights of the individual are on hold and subordinated to political interest. The rights, to access medical services, which normally is not challenged, has been subordinated to the public interest under emergency orders, which require people to remain in isolation. Owing to this uncertainty, regarding the side effects of the Covid-19, the rights of the patients were infringed.

There are also questions about the rights of people who view themselves aggrieved, because of a decision of the government to introduce a lockdown, thus preventing them from exercising a basic right of freedom of occupation. One cannot challenge the administrative decision, in accordance to principles of administrative law or employment law. This also applies to a person who is suffering from a chronic disease and, because the spread of Covid is unable to obtain proper and adequate treatment. Pursuant to patient safety statutes, <sup>16</sup> (s)he is entitled to remedies. If the

<sup>&</sup>lt;sup>15</sup> Supreme Court of Justice Petition 2435/20 **Yedidia Leventhal, Advocate v. The Prime Minister and others** (published in Nevo 7/4/2020).

<sup>&</sup>lt;sup>16</sup> Section 5 of the Patents' Rights Law requires health system to provide patients with adequate and reasonable quality health services.

rights of the patient have been subordinated to the general public interest, (s)he probably will not be entitled to compensation. It is too early to evaluate the scope of the pandemic but first data, from the National Insurance released and show a huge grow in compensation payments to Covid 19 casualties, recognizing them as entitled to work compensation from the State.

Post Covid-19 regulations influenced human rights and subordinated to the decision to shut clinics to all elective treatments other than Covid 19. Patients who need elective treatments, such as fertility treatments could not continue due to an age limit, and, in some cases, women could not persist with the treatments and lost the chance for parenthood, which was considered as a basic human right.

The decrease of human rights, of access to public medical services, limited by budgetary considerations post Corona, namely due to the economic crises, the health system resources will decrease and individuals will need to use costly private health services, in additions to other taxes imposed on them.

Under the National Insurance Act, individuals injured during their employment are entitled to compensation. This includes illness correlated to work, if caused during work. With Covid 19, the question arises where the infection with virus take place did. According to the National Insurance publications, <sup>17</sup>. there is an increase of 500% in claims for compensation. Many of the claims raise a question of causation and, if denied, can leave the person without compensation, without a job and with uncertainty of his/her medical situation, due to the uncertain prognosis. A further infringement relates to a pregnant woman to continue to receive a salary, to the end of their pregnancy, unless her absence is due to pregnancy. What is the case of pregnant women who were infected during her pregnancy?

The main crises is economic and it is yet to come. With one million people seeking for work, no budget and growing unemployment, the damages of Covid 19 may be irreversible. It is too early to evaluate the scope of the pandemic but, first data, from the National Insurance, show a huge grow in compensation payments to Covid 19 casualties, recognizing them as entitled to workers' compensation from the State. Other implications will change the face of society in the years to come.

### 8 Conclusion

The Covid-19 crisis has affords a good opportunity of examining whether this will serve as an historical turning point. The above chapter examined the pre-pandemic status of the health system in Israel, with an attempt to forecast what effect the Covid-19 crisis will have on human rights in general and on patient rights and ethical guidelines in particular.

It is too early to forecast the medical ramification of Covid-19. The prognosis of Covid is vague but early reports show that, post Covid, long term damage will affect children and adults and have a wide spectrum of damage that may include

<sup>&</sup>lt;sup>17</sup> https://www.btl.gov.il/English%20homepage/Pages/default.aspx

heart and renal failure, hearing and neurological damages and psychiatric outcomes. Damage to muscles may also ensue. The assumption that the illness may result in future immunity from the pandemic is currently under review.

The health system in Israel, in common with those worldwide, did not make adequate preparations to foresee and handle the current pandemic, and its economic outcome. There has been a shift from individual autonomy to a national debate of the public interest and other ethical considerations.

The chase to prevent a spread of the pandemic was drastic, constituting an infringement of basic constitutional rights, enshrined in Israeli basic laws, such as freedom of movement, the right to property, freedom of occupation, the right to privacy, freedom of information, freedom of religion and individual human rights.

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 few exceptions (medical or religious). Based on the right to autonomy, Israel did not apply a mandatory vaccination policy, even lately when there was an outburst of measles.

Once a vaccination will be found, it is to be presumed that paternalistic policy will apply, in accordance with the public interests, and vaccination will become mandatory.

The Covid 19 crisis has escalated the use of AI techniques, to track positive Covid carriers (consciously and unconsciously) from spreading the disease, using mobile phones as a tracking machine, and, concurrently, possibly extracting private medical information. This escalation emphasized the dangers surrounding algorithms, making predictions about private information. While existing laws prohibit infringement of privacy, there has been a rapid change in public health interests sacrificing basic human rights principals.<sup>18</sup>

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 make prophesies about the future. This shift of the balance will continue for many years to come until the dangers of the current pandemic are over.

Balancing probabilities, in terms of cost effective damage (direct and indirect), that it has been 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 because of the failures to prepare and anticipate the crises.

The answers, to questions raised in this chapter, concerning pandemic effect on health and ethical issues, will take control of the legal discourse. Public health interests will prevail over the right to autonomy in Israel and worldwide. Once a vaccination becomes available the paternalistic policy will, most likely apply, in accordance with the public interests and the vaccination will become mandatory.

<sup>&</sup>lt;sup>18</sup> Office of the State Comptroller and Ombudsman The 71A Annual Audit Report, Jerusalem | October 2020 . Catalog No. 2020-971A ISSN 0334–9713. https://www.mevaker.gov.il.

Covid has created new opportunities and challenges, and, once a vaccination<sup>19</sup> is found, this will change the world and improve technologies that will adapt humankind to a better place in which to live.

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<sup>&</sup>lt;sup>19</sup> On November 1, 2020 the Biological Institute of Israel started the clinical faze trial on humans and is due to find a vaccination within 9–12 months.