

Legal and Forensic Medicine in Israel

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Jonathan Davies

Abstract

This chapter provides a brief overview of the Israeli healthcare system, covering health and legal aspects, doctor and patient relationships, and patient's rights through the main causes of action in Israel's legal system. It will also examine the role of the expert witness in presenting scientific and forensic evidence in civil and criminal proceedings.

The right to healthcare is recognized as a fundamental right in the Israeli law and consists of many rights scattered among legislation. *Patient's Rights Law* (1996) regulates the rights of the patient and doctor–patient's relations. *National Health Insurance Law* declares the rights of residents to receive basic healthcare services. These basic medical services include specific medical procedures, medical technology, and lifesaving medication that change each year according to budget and other interests. In addition, Public Health Maintenance Organization (HMO) and insurance companies may offer residents supplementary private insurances and provide services beyond this basic basket.

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 where private insurance can supply far better quality health services.

In recent decades, the conservative–paternalistic approach has given way to the autonomy of patient's approach which has enormously changed doctor–patient relationships. This has influenced the structure of healthcare management. Court judgments in medical malpractice law use evidential means to overcome the disparity of knowledge between doctor and patient.

J. Davies

Davies - Korn Law Offices, Jerusalem, Israel
e-mail: davies@med-law.co.il

A medical malpractice claim usually includes three causes of action: negligence of treatment, lack of informed consent due to violation of the duty of disclosure, and an independent cause of action for compensation for the breach of the right of autonomy.

According to Israeli Civil Procedure rules, submission of an expert opinion is necessary to establish medical contentions. Scientific evidence in law is proven by means of expert opinions. Medical proof has to be methodically based and reliable. The adversarial system, in which the parties present their evidence, may create a gap between scientific evidence admissible in court and proving it as a scientific theory recognized by science, contrary to evidence-based medicine.

Scientific evidence, at a trial, has a persuasive power which might affect the results of the trial. For example, DNA evidence has a persuasive power which alone can constitute the sole circumstantial evidence that will lead to the conviction of a defendant in a criminal trial. In civil cases, the expert's opinion is the main tool to prove scientific evidence.

Another means of proving scientific evidence is the use of clinical guidelines which are set as normative standards and used as a tool to reflect the standard of care at the time. These guidelines can be used as a tool for assessment of questionable conduct. Guidelines are consulted by courts because they provide evidence of standards recognized by professional medical organizations. Clinical practice guidelines are of value in systematizing medical procedures, mainly those which may have legal implications.

Introduction

Legal medicine is a dynamic field that covers many issues where science, medicine, and law converge. The topics, in legal medicine, range from protecting the rights of the patients, minors, handicapped, and elderly to issues 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, gene therapy, protection of genetic information, and the dying patient.

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. Protections of a patient's rights in Israel are set by legislation, and some have been created by court ruling. The accepted causes of action in legal medicine are medical malpractice, wrongful life, and informed consent, all of which are governed by the patient's right to autonomy which has been recognized as a constitutional right.

This chapter provides a brief overview of the Israeli healthcare 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. It will examine the role of the expert witness in presenting scientific and forensic evidence in civil and criminal proceedings.

The Healthcare System in Israel

The Israeli healthcare system is considered to be of high quality and economically efficient. Health indicators are comparable with those of developed countries. Life expectancy for males is 79 and for females 82.5 years, and infant mortality is 3.6 per 1,000 live births. Inequalities in health indicators exist with lower scores for those living in the periphery and for minorities.

Population

Israel is a young democracy that received its independence in 1948 (Data taken from Central Bureau of Statistics (www.cbs.gov.il) 25/4/2012). The population of Israel numbers 7.881 million. At the time of the establishment of the state, Israel's population numbered 806,000 residents.

The Jewish population numbers approximately 5.931 million residents (75.3 % of the total population), the Arab population numbers approximately 1.623 million residents (20.6 %), and the population of "others," who are immigrants and their offspring who are not registered as Jews in the Ministry of the Interior, numbers 327,000 (4.1 %). In 2010, over 70 % of the total Jewish population was Israeli-born (over half were second-generation Israeli residents) compared with 35 % Israeli-born residents in 1948.

Legislation

Israel's legal system is based on the common law. Israel has no constitution. The Knesset (Israel's Parliament) 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 law and consists of many rights scattered among many legislations. Among the rights included are the right of privacy, right of dignity, right of equality, right to proper medical care, right of information, right of nursing, right of medical confidentiality, and more.

These rights are regulated by laws which were recognized as having superior status and are 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* which regulates the basic rights for dignity and privacy of a person in the society.

Other legislation protects specific groups in society. *Patient's Rights Law* (1996) regulates the rights of the patient and general physician–patient relations; *Freedom of Information Law* (1998), which allows transparency of information and acknowledges the right of every person to information, is subject to certain restrictions; and *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 minimum medical services basket, via the Health Maintenance Organization (HMO) of which he is a member. Knesset recently 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 of the most dynamic laws and reflects the tension between the declared protection of the *National 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 550 changes in legislation of different and diverse subjects, most of them within the *National Healthcare Law* and some through the *Economic Arrangements Law*, which is brought before the Knesset for ratification, next to ratifying the *Budget Law*, were passed. The majority of the issues which require frequent legislative changes are registration policy, administration, coverage of medical services basket, funding of medical services basket, health tax, resource distribution among the different Health Maintenance Organization (HMO), and others. Additional laws regulate the rights of underprivileged groups in the society, such as the handicapped or minors. For example, the *Equal Rights of Persons with Disabilities Law* 1998 regulates the rights 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, 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 Medical Experimentation Law or Ova Donation Law).

Policy: Since 1995, Israel has operated 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 are provided by four healthcare providers (HMO) that are state budgeted. In addition, these agencies can provide private insurances of all kinds. The health basket is a list of drugs and medical services 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 shall be introduced and which patient is entitled to these free benefits.

Courts are often requested to rule in cases against health funds, which may mean a death sentence in some extreme cases, if patients cannot afford the lifesaving drugs which are excluded from the basket. Courts have wide discretion in interpreting the NHI Act based on moral and judicial values.

Financing: Israel spends about US \$2,200 per capita per year on healthcare, 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 are distributed to four statutory non-for-profit health plans, via a capitation mechanism, adjusted for age.

The medical services are provided by HMO and financed by the government through services in the community and medical institutions. 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 plans are 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.

Organization: The government plays several roles in the health market: (a) a regulator, (b) a direct finance and operational responsibility of geriatrics and psychiatry, and (c) owner and operator of 40 % of hospital beds.

The four health plans supply the actual medical services through owned or bought facilities and personnel. Acute care hospitals are mostly public (95 %).

Workforce: There are 3.7 physicians per 1,000 people. This ratio is beginning to decline due to an inadequate increase in intake in the medical schools. A new medical school was erected in 2012, but corrective measures will become effective in about 10 years. The system also suffers from shortage of physicians in specific specialties and of nurses.

Doctor–Patient Relationship in a Public Health System

The *National Health Insurance Act* (NHI) has shaped the nature of medicine in Israel, as the public health system is based on the possibility of providing medical services, within the scope of limited financial resources, due to the budget changes in the health system which are updated annually. Although the health system is considered formally public, more than half of the population holds additional private insurance.

In addition to the NHI which provides basic medical services, the HMOs and the insurance companies may offer residents private insurances and provide services beyond the basic basket.

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 doctors 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.

There are various models to describe the complex legal relationship between the doctor and the patient [1]. Each of the models balances the obligations to inform and the patient's right to receive substantial information. The balance point has changed over the years: At first, the paternalistic presupposition that the authority to make decisions in the matter of a patient was given solely to the doctor (*Confidential Model*) was prevalent. Later, the patient's right to agree or refuse the treatment was based on information regarding the nature of the treatment (*Consensual Model*). An additional development was made when broad interpretation was given to the patient's right to autonomy. It was 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 educated decision based on such information. 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" [2]. The doctor has the duty to volunteer information to the patient, in addition to the information regarding the nature of the suggested treatment.

Recently, 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 final decision, regarding the appropriate treatment, is eventually made by the patient him/herself. The doctor is obligated to take part in this process and provides all material information that is needed for the patient decision, as stated in the *Matthias* ruling: [3]

"Choosing among medically reasonable treatment alternatives is a shared responsibility of physicians and patients. To discharge their responsibilities, patients should provide their physicians with the information necessary for them to make diagnoses and determine courses of treatment. Physicians, in turn, have a duty to evaluate the relevant information and disclose all courses of treatment that are medically reasonable under the circumstances. Generally, a physician will recommend a course of treatment. As a practical matter, a patient often decides to adopt the physician's recommendation. Still, the ultimate decision is for the patient" [4].

Influence of Legal Judgments on Healthcare Management

In recent decades, the conservative–paternalistic approach has started to give way to a trend which is characterized by “relocating the center of focus from the treating doctor towards the patient, who has been accepted as having the primary role in the process of formulating a decision regarding the medical treatment to be performed on his person. . .” [5].

Israel's Supreme Court has located the balance point – on a scale which has the doctor on one end and the patient on the other end – closer to the patient's side. Chief Justice Shamgar upgraded the patient's right "for self-determination" setting the standard that "a doctor shouldn't perform treatment without patient consent."

Even before the American system turned toward the *reasonable patient doctrine*, Israel's Supreme Court had already decided on that balance point. Chief Justice Shamgar ruled, in the *Rivey* case, that even if the patient has signed a consent form "for any operation, or other medical treatment that the doctor deems necessary to perform during the surgery," this document must be interpreted in a way that is harmonious with the fundamental principle of the patient's right over his body.

The courts indicated that the patient's permission must be obtained before performing any treatment on his/her body, and it is not sufficient to rely on the patient's signature on a consent form as permission to perform any treatment.

This ruling was followed by the *Patient Rights* Law that was enacted in 1996 and has set a high standard of disclosure with regard to the doctor's duty toward the patient. This approach negates the paternalistic approach toward the patient and recognizes his absolute right to autonomy.

The general rule, in Israeli civil law, is that *the burden of proof is on the claimant*, meaning that plaintiff has to establish the existence of certain facts and causes that give rise to his claim, by a preponderance of evidence or proof by clear and convincing evidence, except in cases of evidential uncertainty or when the plaintiff is denied the possibility of proving that the damage was caused due to the defendant's negligence.

The need to overcome the apparent disparity between the doctor and the patient led to the implementation of "evidential means" against the doctor, such as shifting the burden of proof in situations of uncertainty. Courts also developed some evidential presumptions, in order to loosen the rules of causation, while removing compulsory guidelines when determining the existence of causation. An important evidential tool was the creation of the *evidential damage doctrine* which shifts the burden of proof on the defendant if the plaintiff cannot prove his/her case. The root of these developments is in the traditional concept, regarding the said disparity of the doctor–patient relationship, and they were meant to help balance the doctor's control over the information.

There is a need to distinguish between uncertainty regarding the facts that lead to the damage and the reasons (causes) which led to the damage. When defendant's causes uncertainty is caused by the defendant's conduct, Tort Act has set evidential presumptions, such as *Res ipsa loquitur* or procedural and substantive "evidential damage," which can *rebut the presumption* or inference that the defendant was negligent, according to which the burden of proof is shifted to the defendant, and it is on him/her to prove that the damage was not caused by his/her faulty behavior.

The classification of factual uncertainty is through evidence law. Court has discretion to decide on the aggregate of evidence or balance of probabilities, meaning that if the defendant has successfully carried the burden of proof, the claim will be dismissed. If he/she does not carry the burden of proof, the claim will be granted in full and the plaintiff will be awarded compensation.

The duty of doctors, and medical institutions, to take real-time medical records and keep the records was recognized in many verdicts of the Supreme Court. It is cemented in *Patient's Rights Act*, 1996, according to which anyone who performs medical treatments has a duty to document, among other things, *medical information regarding medical treatment the patient has received*. Documentation is very important for the purpose of future treatment of the patient, for the purpose of being able to inform the patient, as he/she has a right to his/her medical records and knowledge of medical treatment he/she was given. When the medical record is missing, the medical institution must explain what actually occurred. In such a case, the burden of proof shifts to the medical institution, and if it does not carry that burden, the suit will be granted.

Court rulings reveal that the courts have solved the problem of factual uncertainty by applying the doctrine of *evidential damage* in its material sense, which may give way to an independent cause of action in torts. The principle, rooted in evidential damage (in its substantive sense), is in shifting the burden of proof not just for failure to keep and properly maintain medical records but also for negligence of a different nature, which causes injury to the plaintiff's ability to prove the basis of his claim. Negligence, on the part of the defendant, by not performing medical tests which had they been performed, could have demonstrated the causes of the damage.

In the *Shukrun* case [6], the court discussed the question of causation, between the disease the appellant contracted and his military service, in light of the nonperformance of tests which should have been performed during the appellant's service. The Supreme Court held that the IDF was liable for failure to perform tests and follow up and shifted the burden of proof to the defendant. The court held that "the evidential damage" not only shifted the burden of proof but also granted entitlement to recompense, meaning it gave the plaintiff an independent cause of action. The holding was also applied to medical malpractice suits. In the *Meir* case [7], the "evidential damage" doctrine, in its substantive sense, was acknowledged as granting an independent cause of action in torts.

The doctrine of evidential damage has two facets: an evidential-procedural facet, concerning the creation and maintenance of medical documentation, and a substantive-tortious facet which grants an independent cause of action in torts due to failure to perform tests which, had they been performed, would have allowed the plaintiff to prove the causation between the negligence and the damage.

In the case of *Estate of Berta Marciano* [8], the significance of the doctrine was shown in a case of "loss of chance," to recover from the cancer that the deceased suffered. In these cases, the plaintiff is entitled to partial compensation, only if he proves that damage is due from the defendant's negligence.

The deceased passed away due to colorectal cancer. It was held that the defendants cannot benefit from the failure in performing the colonoscopy which caused evidential damage that is sufficient to reverse the burden of proof in this case, and if the burden is reversed, there can be no doubt that the defendants did not prove that there is no causation between the negligence and the tragic result.

The change of attitude in concept over the years has led to a significant legal influence on healthcare management. This is demonstrated through evidential means in order to bridge the gap in information due to the disparity of the doctor–patient relationship.

Causes of Action in Israeli Law

Israeli tort law is based on the concept of individual liability. Modern tort law is mainly governed by two categories of torts: negligence and breach of statutory duty. These are both regulated, both in the *Tort Act* and by specific statutes which have a bearing on specific legal medicine issues which determine that violation of that statute constitutes a cause of action.

The Supreme Court has asserted that the test for determining the negligence of a doctor is the *Reasonable Doctor Test*, at the time of the act, and not a hindsight test. The doctor's decisions and actions must conform to the accepted norms in the world of medicine, at the time, norms which are supported in textbooks, by previous experience and by common sense. The attitude, which is prevalent in court rulings, is that *not every mistake in the actions or judgment of the doctor amount to negligence*. "The courts have stated on numerous occasions that failure of a surgery, or damage caused thereby, do not in themselves create a presumption, or a conclusion, of medical malpractice." [9]

A medical malpractice claim usually includes three causes of action: negligence of treatment, lack of informed consent due to violation of the duty of disclosure, and a breach of the right of autonomy. In practice, the three causes are argued together but separately. When negligence of medical treatment is proven (including the elements of damage and causation), there is no point in discussing violation of the duty of disclosure and lack of informed consent. If negligence of medical treatment has not been proven, the court continues to examine the cause of violating the duty of disclosure and lack of informed consent (including the element of damage and causation). If a cause of lack of informed consent is not proven, then the court must turn to measuring the violation of autonomy.

Informed Consent

The *Patient's Rights Act* changed the balance point 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 is considered part of the right for autonomy of the patient, protected by law.

The meaning of informed consent is the doctor's duty of disclosure of information and patient's consent. In order for the patient to give genuine consent to the suggested treatment, he/she needs to be given 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 first 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/she needs, as part of the right to autonomy.

In practice, the doctrine of informed consent has received a broader interpretation, and it is customarily considered to include other elements, in addition to the requirement of consent and the requirement of disclosure, for example, the requirement of understanding the medical procedure and its consequences [10].

The test, adopted by the Israeli courts, for determining the standard of disclosure and its scope is the “Reasonable Patient Test,” which balances, on a case by case basis, the needs and expectations of the patient, with prevention of over-deterrence of doctors, and the assurance of continuous medical practice. The main drawback, to the “Reasonable Patient Test,” is ignoring the individual and unique circumstances of a specific patient, whereas the test applied by the courts is an objective test in the form of the reasonable patient. Some hold that the doctrine of informed consent is used in order to expand the liability of doctors even in cases where no negligence of medical treatment has been proven [11].

In the *Shtandel* case [12], the Supreme Court decided that “our ruling did not accept the American viewpoint, which holds that a doctor fulfills his obligation if he gives the patient information according to standard medical practices, but rather a higher standard of disclosure, which is based on the patient’s needs as a reasonable person.”

The *Sidi* case [13] rejected “the sovereign viewpoint that holds that a doctor has fulfilled his obligation towards a patient of relaying information if he is acting in accordance with standard medical practices. . . .” It was determined that there is no doubt that “the *professional-medical* aspects are of significant importance but the doctors possess the knowledge regarding the various treatments and possible tests. . . .” This standard of disclosure requires a reasonable doctor to take into account these needs as well as the expectations of the reasonable patient.

In a District Court ruling of the *Ravid* case [14], which was a disciplinary appeal, the court applied an even stricter test when ruling that doctors should make decisions based solely on professional–medical considerations, rather than budgetary–administrative considerations. The court ruling has asserted a standard of disclosure, found also in American rulings and accepted in Canada and Australia, which is based on the needs of the patient.

The *Patient’s Rights Act* has rooted the doctrine of informed consent in legislation, but there are still many open questions as it does not expressly specify what the treating doctor must tell the patient who refuses the suggested treatment or selects a different medical treatment. The *Patient’s Rights Act* does not require the doctor to give information about him/herself, such as the following: Is the patient entitled to know that the doctor, treating him, has AIDS or hepatitis B? Is the patient entitled

to receive information regarding the surgeon's experience in performing the suggested operation? Is the patient entitled to know the rate of success of the suggested treatment, at the index hospital, compared to other hospitals, in Israel or abroad?

There are two approaches in Israel's Supreme Court, regarding the question which test should be applied for examining the scope of the duty of disclosure, on the part of the doctor to his 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.

Violation of the Right to Autonomy

Informed consent focuses, first and foremost, on the right of self-determination and autonomy of the individual, as part of the perception of human rights and individual liberties in a democratic-liberal society. In the *Daaka* case, [15] the Supreme Court recognized, for the first time, the right of a patient to be entitled to symbolic compensation for breach of the constitutional right of autonomy. This independent cause of action has developed over the years, and now, courts award substantial awards. In the matter of *Ben David* [16], the District Court awarded compensation for partial negligence of the defendant in a wrongful birth case. The Supreme Court accepted the appeal for award of compensation, based on negligence, but awarded plaintiff's compensation of 250,000 NIS (which is approximately \$60,000 US) for breach of right of autonomy.

As a rule, courts do not award compensation for the breach of the right for autonomy, in addition to damages for bodily harm and nonpecuniary damage caused due to negligence of treatment or due to lack of informed consent. Damages are also not awarded for violation of the right of autonomy, when there has been no damage, namely, when the treatment was successful. This is despite the fact that, theoretically, there is no reason not to award damages for this separately or in addition to compensation for actual damage caused to the plaintiff.

Wrongful Life

The penal code forbids termination of pregnancy, unless a committee, set up by the Ministry of Health, allows the termination for medical reasons of mother or fetus and/or social reasons. Termination of pregnancy could take place any time prior to the birth of the fetus. The Committee for Termination of Pregnancy allows 20,000 terminations a year.

The Supreme Court has recently decided on a cause of action considered as "wrongful life." This is an issue which arises when a person has some form of congenital defect, and it is claimed that careful conduct by the defendants – medical personnel who treated the pregnant mother – would have prevented his birth entirely.

Two separate causes of action may arise due to the negligent conduct: the parents' cause and the cause of the child him/herself. These causes have been acknowledged in the verdict of the Supreme Court in the *Zaitsov* case [17]. The child's cause of action is generally known as "wrongful life," differentiating it from the parents' cause of action, known as "wrongful birth." All five of the judges, presiding over the *Zaitsov* case, held that there is nothing to prevent the parents' cause of action – the cause of "wrongful birth" – in the scope of the negligence tort and in accordance with regular torts principles. The debate revolved around the question of the existence of the child's cause of action. The court, by opinion of the majority, acknowledged the child's cause of action – the cause of "wrongful life." The four justices of the majority disagreed on the theoretical justification for acknowledging the "wrongful life" cause of action and as a result the question of how to assess the damage.

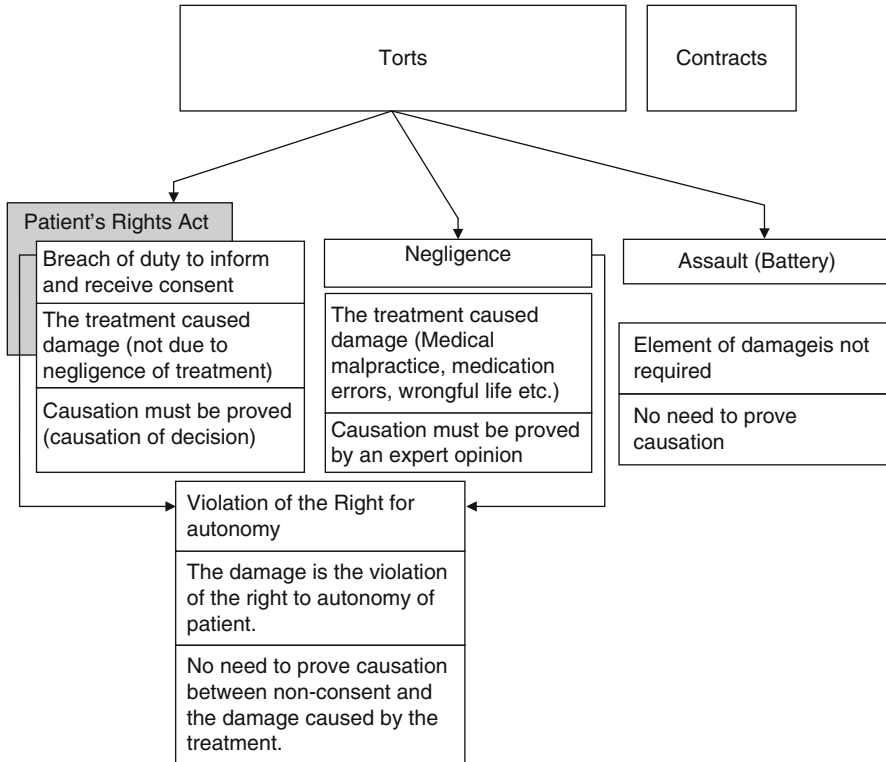
In the *Hammer* case [18], the Supreme Court ruled that the child's cause of action – the "wrongful life" cause – can no longer be recognized by the court. Ruling on these matters led the court to revoke the infant's cause of wrongful life and, to a significant expansion, of the cause of action of the infant's parents. By means of this cause, the parents can be awarded compensation, which will cover the costs of raising and providing for the infant for the rest of his/her life. In this way, the Supreme Court fulfills the cause, rooted in the *Zaitsov* ruling – to award beneficent compensation to cover, as much as possible, the handicapped child's medical, rehabilitative, and caregiving needs – but within the scope of the parents' lawsuit for wrongful birth.

In the issue of causation, the courts ruled that parents must prove the element of causation of their cause of action. In order to prove the causation, between the negligence and the various injuries caused by the child's defect, they must, at first, show that if the Committee for Termination of Pregnancy had had all of the relevant information (information which was not given to the parents due to negligence), the committee would have allowed the parents to terminate the pregnancy. Secondly, and only if the answer to the first question is in the affirmative (otherwise causation is severed in all events), the parents will be required to show that, but for the negligence, they would have actually applied to the Committee for Termination of Pregnancy in order to get approval. It should be emphasized that, whereas it has been proven that the committee would have approved an abortion, even if the parents could not prove that they themselves would choose to terminate the pregnancy, it does not detract from their ability to sue for the damage, caused to them, by the violation of their autonomy, namely, their right to make such an important decision in their lives in an educated way. For this damage, they are entitled to separate compensation.

Regarding the question of the damage and calculation of compensatory damages, the court ruled that the parents are entitled to receive compensation from the defendant for the extra costs needed to cover their child's medical and caregiving requirements, and in the event that their child continues to depend on them due to his/her handicap through adulthood, they are also entitled to compensate for the expenses they incur for him/her for the rest of his/her life.

The Relationship Between the Various Causes of Action

The following diagram represents the different causes of action for breach of rights in the health law system in Israel [19]



Admissibility of Scientific Evidence in the Adversarial System

According to Israeli Civil Procedure rules, submission of an expert opinion is necessary to establish one or more of the essential elements of a civil claim or defense and is a precondition for proving medical contentions. In the criminal context, expert opinion is required to support claims of incompetency or insanity and any medical or scientific argument that is brought to court.

Expert opinion must be prepared by an expert that is a specialist in the disputed issue of the claim, bearing in mind the facts of the case and expressing a professional expert opinion, based on medical practice and experience. The opinion must distinguish between the basic facts and case studies in medical literature.

The expert witness should review all pertinent medical facts and should be supported by the medical records and data collected according to evidence-based medicine (EBM) rules. The expert witness must rely on medical literature and studies, published in scientific textbooks and “state-of-the-art” articles published in well-known medical journals. The role of the expert witness is to explain to the court the medical terminology and base his/her opinion on the facts on a *reasonable degree of medical probability*.

The law makes a legal distinction between “possibility” and “probability.” Expert opinion, based upon “possibility,” incorporates an element of speculation and may not be enough to convince the court. The courts, in Israel, are severe in their admissibility requirements for scientific evidence for the purpose of formulating a legal causal connection. This duty, under Israeli law, is even stricter than in English or American law.

Expert opinion plays a crucial role especially in medical malpractice cases. The role of the court is not to choose which of the evidence, presented to it, is recognized by science; it might accept, as evidence, a scientific theory presented to it that has no basis in science whatsoever and can be considered “junk science” or, at the very least, a theory devoid of scientific foundation that might result in the failure of the judicial proceeding.

Any expert opinion is influenced by unconscious or cognitive bias which might influence the outcome. Therefore, contractual relations, between the interested parties and an expert, create a built-in conflict of interests, between the expert’s loyalty to parties and his/her professional duty to maintain objectivity. Biased research might also influence experts who rely on misleading publications and therefore have a negative impact [20].

One of the drawbacks of the adversarial system is that an expert, on behalf of one of the parties, may feel a “loyalty” to whoever commissioned the opinion, and the opinions, submitted to the court, present the scientific theory that suits the party’s interest and, in the case of a court-appointed expert, the particular school and approach held by the expert which do not of necessity reflect the opinion of all trends in the scientific community in the field contemplated by the opinion, so the court cannot obtain an objective opinion. Reality shows that the debt of loyalty owed by the expert, making the opinion, is relative given to interpretation and the work of distilling the scientific evidence, to enable the court to arrive at the truth, is complex and multifaceted.

Scientific evidence, at a trial, has a persuasive power which might affect the results of the trial. An example is of DNA evidence whose persuasive power can alone constitute the sole circumstantial evidence that will lead to the conviction of a defendant in a criminal trial. It is possible to present many additional examples, in civil law, in which the expert’s opinion has a much more persuasive effect, since the court has no tools to decide, from the evidence submitted to it, which is the best medical opinion in the field under dispute, or whether there is another school of medicine which disagrees with his/her opinion and should be mentioned. This could lead to trial opinions unacceptable to the medical community. In the majority of cases, the screening process of judicial review works smoothly and prevents the court from basing its decision on erroneous sources of information.

Forensic Evidence in Civil Law

The field of forensics is a specific specialty within the many specialties of science and medicine. Forensics refers to the investigative task of documenting the proof of evidence in criminal or civil cases. In criminal proceedings, forensic opinion is needed to establish admissibility of forensic evidence, such as DNA testing. In civil proceedings, toxicologists' opinion is needed to establish probability and causation in exposure to toxins that caused damage.

The courts consider DNA testing to be conclusive evidence, with persuasive power in various fields, such as family law (paternity testing, adoption, child custody, immigration, citizenship, or succession), criminal law (circumstantial evidence to prove a criminal act forensic DNA), and civil law (medical malpractice, prenatal testing, access to genetic services, insurance, and employment claims based on the necessity to prove various types of genetic information).

The performance of DNA tests was permitted recently in Jewish law, after the September 11 events. This was the first time that DNA evidence was used to ascertain that a spouse had died, so as to render a verdict enabling his wife to remarry. From the point of view of Jewish law, the evidentiary value of DNA tests was recognized so much so that it served as one of the bases for permitting the marriage of "Agunot" ("abandoned" wives who have not been declared legally free for marriage) [21].

The Supreme Court, in the *Krishnov* case, considered a toxic tort civil case concerning an employee who suffered from non-Hodgkin's lymphoma [22]. The defendants were found responsible for the damages of the employee, who had worked on the KIBBUTZ GARAGE and was exposed to asbestos while working there for 15 years. He contracted a rare cancer of non-Hodgkin's lymphoma. The Supreme Court rejected the appeal by a majority vote, the main legal disagreement revolving around the question of proving the causal connection between asbestos and the disease developed by the respondent, which had never been proved in the scientific literature.

The majority judges ruled that the absence of scientific proof, of the existence of the aforesaid connection, does not negate the possibility that there is such a connection, since the existence of the causal factual connection, between exposure to asbestos and the plaintiffs rare disease, emerges from the accumulation of a number of circumstances: first, the fact that the employee's disease was cancer, together with the scientific fact, which has already become part of the court's judicial knowledge, that asbestos is a carcinogen; second, the connection found in the medical literature, relying on case studies, between exposure to asbestos and the lymphoma contracted by the employee; third, the employee's ongoing exposure, over the years and many hours a day, to asbestos dust; fourth, the relatively young age (37) at which the employee developed this rare disease, which usually appears when a person is in his/her 60s; and fifth, the high percentage of employees at the respondent's work place who had contracted cancer (7 out of 14).

Although, against this evidence, no medical research has established, as a scientific fact, the existence of a causal connection between exposure to asbestos and the disease contracted by the respondent, the absence of such proof does not

negate the existence of the connection, and the experts, on behalf of the defendant, had no other logical explanation for the outbreak of the disease in this employee, at such an early age.

Forensic Evidence Criminal Law

In the *Abu Hamaad* case, [23] the Supreme Court considered the admissibility of DNA testing. The question was whether a match, between the findings of DNA tests on material taken from a rape victim's body and material taken from the suspect, can be considered as the sole testimony for a conviction in a criminal case.

The DNA evidence, in the *Abu Hamaad* case, does not comply with the requirements of criminal law for convicting a defendant based on circumstantial evidence. The Supreme Court emphasized, in its judgment, the inherent difficulty faced by the court when examining the reliability and weight of DNA testing. It has no real tools of its own to examine this type of evidence, and it relies, to a great extent, on the expert's opinion. The court ruled that, when there are no binding rules for performing the test, the defendant and his representative have no real way of attempting to repudiate its results and conclusions.

The difficulty inherent in the unique character of DNA evidence, combined with the fact that the tests are performed and the conclusions are drawn, not in accordance with binding rules but pursuant to the expert's exclusive discretion, creates an impossible situation where the defendant does not have any possibility of defending him/herself against the DNA evidence and the court does not have the tools enabling it to assess such evidence effectively.

In establishing the new ruling, concerning the weight of the DNA evidence, the court stipulated its conclusions on the fulfillment of two conditions (the possibility of repudiation and compliance with procedures) which are crucial for the reliability of the evidence.

The Use of Clinical Guidelines as a Tool to Prove Medical Evidence

Another mean, in proving scientific evidence, is the use of clinical guidelines which are set as normative standards and used as a tool to indicate the standard of care at the time. They can be used as a tool for assessment of the questionable conduct. Guidelines are consulted by courts because they provide evidence of standards justified in relation to evidence rather than custom. Clinical practice guidelines are of value in systematizing medical procedures, mainly those which may have legal implications, such as the declaration of brain death. In other procedures, guidelines may serve the court as a source of sound information, provided they are recognized by a professional body and proven to bear no relation to a body which may have interests in the delivery of healthcare.

As clinical practice guidelines become more and more prevalent, some authors [24] believe they will define the requisite “standard of care” for medical treatment and impact medical malpractice litigation, and in the long run, they may even replace expert testimony.

An attempt was made to utilize clinical guidelines in court, mainly in medical malpractice litigation. The idea was to try and use the guidelines as the “gold standard” of the particular procedure considered by the court. Such use, under an adversarial system, is hard to conceive. No evidence can be introduced in court unless presented by a witness, who under the circumstances must be an expert, and both the witness and the material introduced by him/her are subjected to cross-examination. Such scrutiny is imperative, in view of the extrascientific interests which may be, and in fact are, involved in many of the published guidelines.

A large number of clinical guidelines exist in different legal systems all over the world. There are substantial differences between high-standard guidelines on the same well-defined clinical entity. The selection of literature data, and diagnostic and therapeutic recommendations, seemed to be influenced by such cultural aspects as habits, the patient’s expectations and the structure of the healthcare system. All authors agree that clinical guidelines do not substitute the discretion of the doctor in any treatment [25].

From the perspective of litigation, the key question has been whether guidelines can be admitted as evidence of the standard of expected practice or whether this would be regarded as hearsay.

Clinical Guidelines in Israeli Case Law

A scientific theory is proven at trial by means of an expert opinion by a specialist in the field relevant to the case, taking account of the facts of the case. The opinion will be filed, by an expert on the issue, who has proven experience, and will rely on the case history, the clinical tests, and the scientific literature relevant to the issue under dispute. The opinion must distinguish between the basic facts and the results of the work of medical experts.

The plaintiff, in a medical malpractice claim, is entitled to present the relevant guidelines to prove that the defendant doctor breached the clinical guidelines and therefore is liable. This was the case of *Hazon* [26]. The plaintiff, 34 years old, requested her family doctor to refer her for a mammography test, due to family history of breast cancer. The doctor refused, claiming that the optimal age for mammography in her case (family history) is 45. Two years later, after detecting a lump in her breast, she was referred for a mammograph which detected breast cancer followed by mastectomy.

According to the Family Doctors Association and the National Cancer Association guidelines, it was recommended that women with family history should undergo a mammograph at the age of 40. The court found that these clinical guidelines, as a reflection of common practice, could be a directive but certainly do not substitute the doctor’s discretion.

The Supreme Court in the case of *Ravid Moshe* [27] demonstrates this approach. Ravid, a five-year-old girl, was given a local anesthetic to her gum, for the completion of a dental filling. Shortly thereafter, neurological symptoms became apparent. On admission to hospital, brain infarction was diagnosed. The neurological damage persisted – permanent neurological impairment, physical as well as cognitive.

The Supreme Court established its recognized principle that the standard of medical practice is a matter for the court, not to be decided or “accepted” by a “respectable body of members of the medical profession.” It was emphasized that the standard of practice is established, taking into consideration a variety of interests of importance to the public. In view of the severity of the possible consequences, the failure to use equipment which would have enabled the prevention of the calamity was found deficient, namely, negligent.

The Supreme Court indicated that, according to the guidelines set by the manufacturer of the dental syringe, “To avoid inadvertent intravascular injection an aspiration check should be performed.” This was not done, and therefore the dentist was found negligent. The Supreme Court indicated that clinical guidelines set a minimal standard of care used as an additional tool to measure legal liability.

A different issue is the control of the regulator (namely, the Ministry of Health) to dictate the standard of care, through the clinical guidelines, in cases where there is a medical dispute in the specific issue. In cases of dispute, the guidelines should refer to the different schools of thoughts and not state the preferred standard of care.

Clinical Trials Guidelines or Expert Witnesses Testimony: Who Will Prevail?

Under common law, the minimal acceptable standard of care is measured according to responsible medical practice. Clinical guidelines have played a subsidiary role in determining the required standard of care. It is expert medical evidence that primarily assists courts in determining the required standard of care. Some authors believe that they define the requisite “standard of care” for medical treatment and impact medical malpractice litigation.

Standard of care in clinical trials is based on Harmonization Good Clinical Practice (ICH-GCP) guidelines, as a required source of direction for physician–investigators. The ICH-GCP guidelines were designed to represent an ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

Most protocols, clinical trials contracts, and research agreements bind physician–investigators to ICH-GCP directives. The high-profile and widespread reliance on ICH-GCP guidelines suggests that expert witnesses may be very likely to rely on them in the construction of a standard of care for human research activity.

This multiple relationship raises questions concerning the weight that should be given to expert witness’ testimony that does not comply with clinical trial guidelines.

Courts have already accepted the introduction of practice guidelines, by expert witnesses, as evidence of the standard of care, in traditional medical malpractice cases. If courts accept the introduction of similar evidence by experts in research suits, the relevant guidance documents will essentially be given the weight of law by their inclusion into the standard of care in that particular case. Physician–researchers’ conduct in clinical trials will be measured against the requirements of the codes accepted by courts as valid articulations of researcher responsibility.

The researcher–participant relationship creates additional duties – duties that derive specifically from the fiduciary/trust relationship between the physician–researcher and patient–participant. This portion of the standard of care can only be articulated by expert witnesses, at trial, who will describe to the court how a reasonably prudent physician–investigator would act, in the same or similar circumstances – what researchers view as prevailing responsible practice in clinical trials.

Ready Reckoner

- The Israeli health care system is considered to be of high quality and economically efficient.
- The right to health care is recognized as a fundamental right in the Israeli law and consists of many rights scattered among many legislations.
- *National Health Insurance Act* declares the rights of residents to receive basic healthcare services and supplementary private insurance.
- *Patient’s Rights Act* regulates the rights of the patient and general physician–patient’s relations.
- Doctor and patient relationship balances between the patient’s right to receive substantial information and doctor’s obligations to disclose all relevant the full.
- The final decision, regarding the appropriate treatment, is eventually made by the patient.
- The doctor is obliged to take part in this process and provide all material information that is needed for the patient decision.
- The Supreme Court in Israel adopted the *The Shared Decision Making Model* that perceives the doctor and the patient as two parties who share making the decisions which will be best for the patient.
- Disparity of knowledge between the doctor and patient led to the implementation of *evidential means* against the doctor, such as shifting the burden of proof in situations of uncertainty.
- The principle, rooted in evidential damage, is in shifting the burden of proof due to failure to keep and properly maintain medical records.
- The doctrine of evidential damage grants an independent cause of action in torts, due to failure to perform tests, which, had they been performed, would have allowed the plaintiff to prove the causation between the negligence and the damage.

- A medical malpractice claim usually includes three causes of action: negligence of treatment, lack of informed consent due to violation of the duty of disclosure, and an independent cause of action for compensation for the breach of the right of autonomy.
- The test for determining the medical malpractice is the *Reasonable Doctor Test*.
- The doctor's decisions and actions must conform to the accepted norms in the world of medicine, at the time, norms which are supported in textbooks by previous experience and by common sense.
- The *Patient's Rights Act* changed the balance point 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.
- Informed consent reflects the right of self-determination and autonomy of the individual.
- Israeli courts awarded compensation for violation of the right of autonomy, even when there has been no damage, namely, when the treatment was successful.
- Expert opinion plays a crucial role especially in medical malpractice cases. Scientific evidence in law is proven by means of expert opinions.
- Medical proof has to be methodically based and reliable.
- The adversarial system may create a gap between scientific evidence, admissible in court, and proving it as a scientific theory recognized by science, contrary to evidence-based medicine.
- Scientific evidence, at a trial, has a persuasive power which might affect the results of the trial.
- In civil cases, the expert's opinion is the main tool to prove scientific evidence.
- In criminal procedures, DNA evidence has a persuasive power which alone can constitute the sole circumstantial evidence that will lead to the conviction of a defendant.
- Clinical guidelines are consulted by courts because they provide evidence of standards recognized by professional medical organizations.
- Clinical practice guidelines are of value in systematizing medical procedures, mainly those which may have legal implications.

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