I. What is health (medical) law

Health care and medical profession are the subject of both medical deontology and legal regulation. In general, law is the body of rules (usually legislation, statutes) imposed by a State upon its inhabitants (population) which is designed to regulate human conduct within that State. The courts or the authorities within the public governance (e.g. Ministries) interpret these rules of conduct, decide whether they have been broken and pass sentence or make an award of compensation. A certain standard of behaviour is thereby maintained amongst the members of the State in the interest of the common good.

In comparison, medical ethics is consisting of rules created, maintained and controled by the professional community itself.

Rights and obligations of the health worker (employee) and the employer (e.g. hospital), based on a contract of employment, are subject of regulation of labour law and overlap with health law.

Scope of health law:
- Outlines what the government and professional bodies (chambers) can/can not do
- Sets the rules to settle and solve conflicts within health care
- Training, education, licensing, regulation of health care professionals
- Rights of patients and regulation of doctor (provider of care) - patient relationship
- Protection of privacy, personal data, confidentiality, disclosure. Availability (geographical, financial) and quality of health care services
- Regulation of financial flows within health care system, Health insurance issues
- Advertising of services, Biomedical research
- Legal Instruments to regulate smoking, other health threats etc.

Levels of legal regulation:
1. Supranational
   a) global (treaties by United Nations, WHO, International Red Cross) = international law
   b) regional (European Union, KBSE, Council of Europe, League of Arabian States...)
2. National legislation of a particular state (laws of a State)

Where to find sources of law: official websites of the legislators
National, E.g. Collection of laws of the SR, or Collection of decrees of Ministry of Health.
International: E.g. Conventions of the Council of Europe: www.conventions.coe.int
II. Core international conventions important for health care:


2. “Convention on the rights of the child“ (adopted by UN in 1989) sets e.g. these rules: childhood is entitled to special care and assistance. States Parties shall take all appropriate legislative, administrative, social and educational measures to protect the child from all forms of physical or mental violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation, including sexual abuse, while in the care of parent(s), legal guardian(s) or any other person who has the care of the child. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care; develop preventive health care, guidance for parents.

3. “Convention on the rights of persons with disabilities“ (adopted by the UN in 2006) The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.


Some of rules: The interests and welfare of the human being shall prevail over the sole interest of society or science. States as the treaty parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality. Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards. The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

All of above mentioned rules have direct impact on health care practice.

III. Malpractice in health care

Legal liability is the responsibility of someone for wrongdoing. In health care, it is responsibility of a health care professional for harm caused to a patient by malpractice.

Medical malpractice is a doctor’s failure to exercise the degree of care and skill that a physician or surgeon of the same medical specialty would use under similar circumstances. Medical malpractice occurs when the treatment provided by health care professionals falls below the acceptable standard of care, causing serious personal injuries. Medical malpractice occurs when a patient is harmed by a doctor (or other health care professional) who fails to perform his or her medical duties. Law governs the liability of doctors and other treatment providers when they cause harm to a patient by rendering their services in a negligent manner. Like other areas of professional malpractice, medical malpractice is a form of negligence.

Medicine has no officially sanctioned or exact definition of error, and the working ideas held by individual physicians on this subject vary widely. Standards require that physicians provide reasonable care under the circumstances, as judged against the level of knowledge and skill exercised by their professional peers. Malpractice is the error by negligence.

Negligence is a common claim brought against a health care provider in a malpractice action. In order to prove negligence against a doctor, the patient must allege and prove four components:

1. Professional duty to take the action: First, the patient must prove that the health care professional owed a duty of care to the patient.
2. Once that is established, in the second component the patient must prove that the doctor breached that duty of care. „Standard of care“ is not a state law or regulation, but a legal concept that provides common limits that a doctor must comply with in a given situation. Often, standard of care is defined by the professional guidelines.
3. Harm suffered: Third, there must be an injury to the patient. Many victims of medical malpractice suffer death or serious injuries such as nerve damage, chronic and debilitating pain, unnecessary operations etc.
4. Causality: Finally, the injury must be proximately caused by the breach of the doctor’s duty of care.

Examples of medical malpractice:

- Failure to inform the patient of all available treatment options and the associated risks and benefits related to each
- Failure to refer to a specialist
- Negligence in failing to properly diagnose
- Incorrect use of anesthesia resulting in complication or even death
- Improper procedures which result in injury and damage
- Misreading X-rays
- Birth Injuries and Obstetric Malpractice
- Inadequate monitoring of the patient's condition
- Failing to diagnose or control an infection
- Use of faulty materials or products
- Medication error

Medical malpractice claims are typically claims brought against an individual physician for negligence, or claims brought against a medical institution. Hospitals can also be held liable for the conduct of their staff. However, most medical malpractice claims arise from an unfavorable interaction with the doctor or nurse and not necessarily from a poor treatment outcome.

The victims of medical malpractice seek compensation for their physical or emotional injuries, or both, through a negligence action. Expert witnesses and expert opinions play a key role in medical malpractice lawsuits.

In malpractice claims, compensation for present and future medical expenses, diminished quality of life, lost wages, pain and suffering of a patient is usually asked. Many health legislations worldwide impose to health care providers a mandatory duty to have a malpractice insurance.

IV. Medical documentation (medical file, patient records)

The medical profession has an ethical and legal responsibility for patient care. A properly maintained patient record is a very important aspect of this patient care. It is also very important that all x-rays be preserved as well as progress notes, copies of prescriptions, copies of referral slips, missed appointments, etc. Medical documentation is essential for doctor and patient protection, and its maintenance is considered both ethical and legal obligation of the doctor. The duty to protect medical records is a part of medical confidence and belongs to main legal obligations imposed on physicians and other healthcare providers.

The role of medical documentation in health care is:

- **Clinical**, because clinical records are fundamental for delivery of good care, for ensuring continuity and completeness of treatment. Enable monitoring of the patients’ health state and can also be used to aid motivation in preventive practices.

- **Ethical**, because it satisfies the duty of care that the doctor has toward his patient.

- **Legal**, as it is an investment for future protection against medico-legal complications. Once a conflict with a patient or a malpractice action is claimed, doctors will have a better legal defense if all steps in diagnosis, treatment and all aspects of care involving informed consent are documented.

- **Forensic**, as physicians and dentists could play a vital role in assisting forensic investigators in providing information that would help in the identification of perpetrators or victims of crime and natural or manmade disaster situations. This information would be easily available and accessible through well-maintained patient records under health care.
V. **Informed consent**

Informed consent is a legally required, mandatory element of patient care in developed countries. Informed consent should be a written document (a consent form) and is a part of a medical documentation. Consent form signed by a patient before surgery performed is a legal obligation. The lack of informed consent can be at the start of legal action (e.g. lawsuit) against the health care provider.

Patients must be informed as to: the proposed treatment and its benefits, the risks of the proposed treatment, alternative treatments, the patient’s prognosis and the cost of the proposed treatment.

Whenever possible, it is recommended to health care professionals to give alternative treatment plans, and tell the patient which ones is considered to be superior and for what reasons.

People are less likely to feel anxious when they feel in control of their situation. This will help to establish confidence in the medical profession.

**In order to give consent to a proposed treatment, the patient must be completely informed.** Patient relations will be improved through informed consent, as the patient will realistically know what to expect from a given procedure.

**Recommended reading:**
