LAW REGARDING MEDICAL PRACTICE

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Abstract

Medical education anywhere in the world is governed by various legislations applicable to different nations, regions, cultures and religions. Medical teaching is incomplete without creating awareness of these legal responsibilities to the budding doctors. Definitions of various legally relevant medical terms like bio ethics, eugenics, euthanasia, consensual activity, legal rights, freedom of information, consumer protection, lack of communication, confidentiality, hospital accreditation, truth telling, conflict of interest, referral, fee splitting, treatment of relatives, sexual relationships, substituted judgment, vendor relationships, medical futility, legal parties, medical negligence, expert testimony, damages, medical record, privacy law, quality of life (QoL) and reproductive rights are detailed. The laws of medical practice pertinent to India are given in the end of the paper.

Keywords: medical ethics, legislation, medical laws, legal rights, communication, consent, confidentiality

Full text, with all subsections and illustrations

INTRODUCTION

Medical law concerns the responsibilities of medical professionals towards the patient and rights of the patient. The first recorded medical law was the code of Hammurabi, which said; "If a physician make a large incision with the operating knife, and kill him, his hands shall be cut off." When I was talking to a group of present day surgeons about this, the immediate comment was that there would be no body in the hall except the hall boys who would have hands! Thus the need for the medical laws arose due to errors and injustice done to the society purposely or inadvertently. Ignorance of knowledge is not a crime, but negligence is. So over the years, several laws had to be enunciated to protect the society against the harms from the medical profession.

Medical ethics is the study of moral values and judgments as they apply to medicine, encompassing history, philosophy, theology, and sociology. The earliest evidence of professional oath is recorded in the 12th-century in the Byzantine manuscript. These may be traced to guidelines for physicians in the Hippocratic Oath, early Christian teachings, Formula Comitis Archiatrorum, Muslim medicine, Jewish thinkers, Roman Catholic scholastic thinkers Catholic moral theology. These intellectual traditions continue in Catholic, Islamic and Jewish medical ethics.

Thomas Percival, a British physician and author, crafted the first modern code of medical ethics in 1794 and expanded it in 1803. In 1815, the Apothecaries Act of the United Kingdom introduced compulsory apprenticeship. In 1847, the American Medical Association adopted its first code of ethics. In the 1960s and 1970s, building upon liberal theory and procedural justice, much of the discourse of medical ethics
went through a dramatic shift and largely reconfigured itself into bioethics. Since the 1970s, the growing influence of ethics in contemporary medicine can be seen in the increasing use of Institutional Review Boards, the hospital ethics committees and integration of ethics into many medical school curricula.

Values in medical ethics were recognised as four principles, respect for autonomy (the patient has the right to refuse or choose treatment), beneficence (the doctor should act in the best interest of the patient, non-maleficence - "first, do no harm" (primum non nocere) and Justice (fairness and equality). Other values include respect for the patient, (right to be treated with dignity), truthfulness and honesty (informed consent) moral values in conflict (conflict of interest)

**Bioethics** is the study of controversial ethics brought about by advances in biology and medicine. The term was first coined in 1926 by Fritz Jahr, to involve research involving animals. Later it included important issues like abortion, euthanasia, surrogacy, organ donation, cloning, gene therapy and human genetic engineering. Religion plays an important role in bioethical issues. Many rules and guidelines issued with the viewpoint of different faiths like hindu, christian or muslim. A rigid distinction between religion and philosophy does not exist.

**LEGAL TERMS USEFUL FOR DOCTORS**

**Assault (tort)** is intentionally attempting or causing a harmful or offensive contact with the specific intent to cause physical injury. It can be justified in the context of a sport where consent is implied.

Human population control. India's state of emergency between 1975 and 1977 included a family planning initiative that began in April 1976 through which the government hoped to lower India's ever increasing population by compulsory sterilization

**Eugenics** programs are intended to prevent the reproduction and multiplication of members of the population considered to be carriers of defective genetic traits. The Nazis had many other eugenics-inspired racial policies, including their "euthanasia" programme in which around 70,000 people institutionalised or suffering from birth defects were killed.

**Euthanasia** refers to the practice of intentionally ending a life in order to relieve pain and suffering.

**Consensual activity.** Any activity where consent is obtained by fraud amounts to criminal act. Eg having unprotected sexual intercourse,

**Legal right to cause injury.** Doctors have a general right to assume a patient's consent for necessary treatment. So if a person is brought into a hospital unconscious, surgery to preserve life will not be unlawful. But, if the health authorities have actual notice that the patient does not consent, even necessary treatment will be unlawful unless either it becomes urgently necessary to take action to avoid death, or consent is given either by a spouse or relative, or by a court. When in doubt, consent should be sought from the courts. In any event, treatment will only be lawful if it is of therapeutic rather than cosmetic value.

**Freedom of information** is a fundamental human right recognized in international law, This may also refer to the right to privacy in the context of the advancements in information technology.
Consumer protection. The consumer should have access to adequate information to enable making informed choices according to individual wishes and needs.

Confidentiality is commonly applied to conversations between doctors and patients. Legal protections prevent physicians from revealing their discussions with patients, even under oath in court.

Lack of communication. Communication breakdowns between patients and their healthcare team, between family members, or between members of the medical community, can all lead to disagreements and strong feelings.

Hospital accreditation requires that ethical considerations are taken into account, for example with respect to physician integrity, conflict of interest, research ethics and organ transplantation ethics. Various ethical guidelines include the Declaration of Helsinki, ‘Good Medical Practice’ statement, ethics committees with five or more members (healthcare professionals, philosophers, lay people, clergy, one scientist)

Truth-telling Some cultures do not place a great emphasis on informing the patient of the diagnosis, especially when cancer is the diagnosis. American culture rarely used truth-telling especially in medical cases, up until the 1970s. In American medicine, the principle of informed consent now takes precedence over other ethical values, and patients are usually at least asked whether they want to know the diagnosis.

Online business practices. The delivery of diagnosis online leads patients to believe that doctors in some parts of the country are at the direct service of drug companies. Finding diagnosis as convenient as what drug still has patent rights on it. Physicians and drug companies are found to be competing for top ten search engine ranks to lower costs of selling these drugs with little to no patient involvement.

Conflicts of interest. Physicians should not allow a conflict of interest to influence medical judgment. In some cases, conflicts are hard to avoid, and doctors have a responsibility to avoid entering such situations. However, research has shown that conflicts of interests are very common among both academic physicians and physicians in practice.

Referral. Doctors who receive income from referring patients for medical tests have been shown to refer more patients for medical tests.

Fee splitting. Payments of commissions to attract referrals of patients is considered unethical and unacceptable.

Vendor relationships Doctors can be influenced by drug company inducements, including gifts and food. Industry-sponsored Continuing Medical Education (CME) programs influence prescribing patterns. Many patients surveyed in one study agreed that physician gifts from drug companies influence prescribing practices. A growing movement among physicians is attempting to diminish the influence of pharmaceutical industry marketing upon medical practice, as evidenced by ban on drug company-sponsored lunches and gifts.
**Treatment of family members.** Many doctors treat their family members. Doctors who do so must be vigilant not to create conflicts of interest or treat inappropriately.

**Sexual relationships** Sexual relationships between doctors and patients can create ethical conflicts, since sexual consent may conflict with the fiduciary responsibility of the physician. Doctors who enter into sexual relationships with patients face the threats of deregistration and prosecution. In the early 1990s, it was estimated that 2-9% of doctors had violated this rule. Sexual relationships between physicians and patients' relatives may also be prohibited in some jurisdictions, although this prohibition is highly controversial.

**Medical futility.** What should be done if there is no chance that a patient will survive but the family members insist on advanced care? The "expressed wishes" of the patient are documented in these directives, and this provides a framework to guide family members and health care professionals in the decision making process when the patient is incapacitated.

**Substituted judgment** is the concept that a family member can give consent for treatment if the patient is unable (or unwilling) to give consent themselves.

Medical malpractice is professional negligence by act or omission by a health care provider in which the treatment provided falls below the accepted standard of practice in the medical community and causes injury or death to the patient, with most cases involving medical error. Standards and regulations for medical malpractice vary by country and jurisdiction within countries. Medical professionals may obtain professional liability insurance to offset the risk and costs of lawsuits based on medical malpractice.

**The parties.** The plaintiff is the patient. The defendant is the health care provider. A plaintiff must establish all four elements of the tort of negligence for a successful medical malpractice claim - A duty was owed, a duty was breached, the breach caused an injury: The breach of duty was a direct cause and the proximate cause of the injury. Without damage (losses which may be pecuniary or emotional), there is no basis for a claim, regardless of whether the medical provider was negligent. Likewise, damage can occur without negligence, for example, when someone dies from a fatal disease.

**Expert testimony.** An expert must have sufficient knowledge, education, training, or experience regarding the specific issue before the court to qualify the expert to give a reliable opinion on a relevant issue.

**Damages.** They include compensatory and punitive damages. Compensatory damages are both economic (expenses) and non-economic (loss of vision, loss of a limb or organ, loss of a loved, severe pain and emotional distress). Punitive damages are only awarded in the event of wanton and reckless conduct.

**Medical record,** includes a variety of notes entered over time by health care professionals, recording observations and administration of drugs and therapies, orders for the administration of drugs and therapies, test results, x-rays, reports, etc.
Privacy law refers to the laws which deal with the regulation of personal information about individuals which can be collected by governments and other public as well as private organizations and its storage and use.

Quality of life (QoL) is the perceived quality of an individual's daily life, that is, an assessment of their well-being or lack thereof. This includes all emotional, social, and physical aspects of the individual's life. It is an assessment of how the individual's well-being may be affected over time by a disease, disability, or disorder.

Reproductive rights are legal rights and freedoms relating to reproduction and reproductive health.

LEGISLATION AND LAW

This refers to statutes, regulations and other legal instruments which are used in a particular country. To mention some of the important laws, the laws about abortion, prenatal sex determination, radiation protection etc. These laws may be international, national, regional or religious laws. International laws are not complete because of vast variations in the concepts of the different countries and the sovereignty of each country. Hence national laws are more relevant for today’s discussion. Some of the important laws pertinent to the Indian medical practitioner as detailed below in alphabetical order.

MEDICAL LAWS & ETHICS IN INDIA

Adulteration of drugs (IPC Sec 274)
AERB safety code 2001
AICTE rules of physiotherapy
All India council for Technical Education ACT 1987
Anatomy Act 1957
Apprenticeship Act 1961
Arms Act 1950
Atomic energy regulatory body approval for radiology Act 1962
Atomic energy (safe disposal of radioactive waste) rules 1987
Biomedical medical waste management handling rules 1998/2000
Birth and death and marriage registration act 1886
Blood bank regulations under Drugs and cosmetic rules 1999
Breeding of and Experiments on Animals Amendment Rules 2005
Business Rules 1975/1976
Central excise Act (for permit to use and store sprit) 1944
Central sales Tax Act 1956
Charitable and religious trust Act 1920
Cigarettes and other Tobacco products distribution) bill 2003
Clinical Establishments Bill 2010
Companies Act 1956
Consent
Consumer protection Act 1986
Contract Act 1982
Control and Supervision of Experiments on Animals (CPCSEA).
Co-operative Hospital Complex and the Academy of Medical Sciences Act 1997
Dental council of India regulations 2006
Dentists Act 1948
Dentists (code of ethics regulation) 1976
Disaster Management Act 2005
DMC sanitation and public health Bye laws 1959
Drugs and cosmetic Act 1940, 1945, 1982, 2005
Drugs and magic remedies (objectionable) advertisements Act 1954
Drugs control Act 1950
Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act 1982
Electricity rules 1956
Employees provident fund and misc provision Act 1952
Employment exchange (compulsory notification of vacancies) act 1959
Environment protection Act 1986, 1996
Epidemic disease Act 1897
Equal remuneration Act 1976
ESI Act 1948, 1950
Explosive Act 1884 (for diesel storage) 1884
Eyes (Authority for Use for Therapeutic Purposes) Act 1982
Fire Prevention and Fire Safety Act 1986
Fire safety rules 1987
Fire Service Act 2007
Foreign Exchange management Act 1999
Gas cylinder Rules 2004
Guardians and wards Act 1890
Homoeopathy Central Council Act 1973, 2002
ICMR rules governing Medical Research
ICN Code of ethics for nurses
Income Tax ACT 1961
Indian Boilers Act 1923
Indian Evidence act (disclosure of privileged / confidential patient related information before a court of law – under protest)
Indian fatal accidents Act 1955
Indian lunacy Act 1912
Indian medical council Act 1956
Indian medical council (professional conduct, etiquette and ethics) regulations, 2002
Indian medical degrees Act
Indian nursing council Act 1947
Information Technology Act 2000, 2008
Insecticide Act 1968
Insurance Act 1938
IPC sec 269 (negligent act likely to spread infection or disease)
IPC sec 278 (making atmosphere noxious to health
IPC Sec 336 (act endangering life and personal safety of others)
IPC Sec 337 (causing hurt by act endangering life and personal safety of others)
IPC Sec 338 (causing grievous hurt)
IPC section 269
IPC section 52
IPC section 80
IPC section 89
IPC section 92
IPC section 93
Law Governing Management of Patients
Law Governing Professional Training and Research
Law Governing Storage / Sale of Drugs and Safe Medication
Law Governing Biomedical Research
Law Governing Medico Legal Aspects
Law Governing Professional Training and Research
Regulations Governing the Business Aspects of Hospital
Laws Governing the Employment of Manpower
Law Governing the Safety of Patients, Public and Staff within the Hospital Premises
Law of privileged communications
Law of torts
Law Related to Commissioning of Hospital
Laws Governing the Qualifications / Practice and Conduct of Professionals
Laws of contract section
Lepers act 1975
License for possession and use of Rectified / denatured spirit
Lifts Act 1939, 1942
Malaria and other mosquito Borne disease Bye Law 1975
Manual for control of hospital associated infections
Maternity Benefit (Amendment) Act 2008
MCI rules for internship training
Medical Registration (Amendment) Act 2003
Mental Health Act 1987
Minimum Wage Act 1948
MTP Act 1971, 1997
Municipality to Local Authority
Narcotics and psychotropic substances Act 1985
National board of examinations Rules for DNB training
National guidelines for clinical management of HIV / AIDS
Negligent conduct with regard to poisonous substances (IPC Sec 284)
Negotiable instrument Act 1881
Noise pollution control Rules 2000
Nursing council Act 1997
Nursing Council of India Rules for staring school / college of nursing
Nursing home registration Act 1949, 1953, 1959, 2005
Official Secrets Act 1923
Payment of bonus Act 1965
Payment of Gratuity Act 1972
Payment of wages Act 1936
Persons With Disabilities Act 1995
Petroleum Act + storage Rules 2002
Pharmacy Act 1948
PNFD Act 1994
PPF Act 1968
Pre conception and prenatal diagnostic techniques Rules 1996
Prevention of food adulteration Act 1954
Prevention of violence and damage or loss to property Act 2008
Professional Colleges or Institutions (Prohibition of Capitation Fee)
Prohibition of smoking in public places Rules 2008
Prohibition of Violence against Medicare Service Institutions Act 2009
Protection of Human Rights Act 1993
Radiation protection certificate for radiology dept from BARC
Radiation protection Rules 1971
Radiation surveillance procedures for the medical application of radiation 1989
Red Cross Society (Allocation of Property) Act 1936
Registration Act 1908
Registration of birth and deaths act 1969
Registration of medical practitioners with state medical councils
Regulations Governing The Business Aspects of Hospital
Rehabilitation Council of India (Amendment) Act 2000
Rehabilitation Council of India Act 1992
Retail drug license
Rules for display of Red Cross Insignia
Rules for insurance cover for the sterilization cases
Rules for provision of safe drinking water
Rules for provision of uninterrupted power supply
Rules regarding the safe discharge of effluents in the public sewers / drains
Sales of adulterated drugs (IPC Sec 275)
Sales of drug as different drug or preparation (IPC Sec 276)
Sales of goods Act 1930
Shops and factories Act (for national holidays)
Society registration Act 1960
St. John Ambulance Association (India) Transfer of Funds Act 1956
TDS Act
Transplantation of human organ Act 1994/1995
Vaccination Act 1880, 2001
Water (prevention and control of pollution) Act 1974
Weekly Holidays Act 1942
SUMMARY

The above mentioned regulatory strategies are meant to be used to ensure people’s health and safety. The medical fraternity is expected to consider these as responsive regulation, meaning that the strategies for implementation should include voluntary compliance (without any coercion), self-regulation (voluntary code of practice), economic instruments (incentives for health care providers), meta-regulation (external regulatory body to ensure implementation of safety and quality practices) and command and control mechanisms (enforcement by Government).
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