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Chapter 20

Ethics, Legality, and Education in the Practice of Cardiology

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20.1 INTRODUCTION

Cardiology is a branch of medicine characterized by state-of-the-art biomedical technology. Evidence-based medicine is incorporated in the practice of cardiology. Ethical dilemmas known to the specialty arise from the decisions to be made between what can be done and what should be done for varieties of cardiovascular pathologies. Some of the ethical deliberations are resurrection of a patient with acute coronary syndrome or malignant arrhythmias. 1 The practice of cardiology is increasingly constrained by guidelines, regulations, and legal considerations. 2 All doctors, including cardiologists, have a primary duty of care to individual patients, in addition to their responsibilities to society, institutions, and colleagues. Among cardiologists, the propensity to test and treat is closely associated with fear of malpractice suits. 3

Cardiology practice has gained importance as a result of the introduction of advanced diagnostics, drugs, and devices. Early recognition and appropriate intervention minimizes the consequences of cardiac illnesses, which in turn reduces the cardiovascular mortality and morbidity. At the same time, awareness about cardiac care among community members has increased their expectations. When the expectations are not achieved, legal issues creep in. In an analysis of 1899 judicial sentences related to cardiology in Spain, 31% of the decisions were made for plaintiffs and the defects were misdiagnosis including gaps in communication and informed consent. 4,5

Misuse and unethical practices related to state health insurance in India was reported by a weekly magazine, 6 and it urged medical associations to curtail such violations. Factors linked to malpractice claims are patient dissatisfaction,
lack of physician communication, and poor interpersonal skills. The trial attorneys believe that the threat of litigation makes doctors discharge their services more safely. A deep-seated tension exists between the malpractice system and the goals and initiatives of patient safety. Interestingly, improvements in patient safety have been accompanied by an increase in claims of professional medical liability. The number of medical negligence cases against doctors, hospitals, and nursing homes is increasing day by day, globally.

Ethical analysis in general is accused of being abstract and abstruse, as practitioners face difficulties in making decisions while handling cardiac emergencies. At the same time, analysis of the moral concepts of clinical problems, issues, challenges, and arguments among professionals based on scientific evidence help to move the field forward and/or provide clarity. Doctors face ethical complexities among the cases handled by them, and while most of the issues are very similar, they receive less attention or go unnoticed, are not recorded, and are rarely documented. Because ethics pervades all areas of practice in one or other way, it has to be considered, realized, studied, and practiced.

Medicine, law, and social values are dynamic. New additions are constantly incorporated into health laws because of new issues and technological advances. The American College of Physicians Ethics Manual covers emerging issues in medical ethics and reiterates ethical principles. Moral principles form the basis for ethics and are incorporated into the ethical rules of different professions. Historically, the practice of medicine was subject to legal restrictions in ancient Egypt. Also the right to practice was restricted to certain members. Doctors had to learn and follow certain percepts laid down by their predecessors. All these were practiced probably with an intention to protect the public from quackery.

Although many professions deal with people who are in vulnerable states and have access to the inner lives of other human beings through service or trust, the impact of medical service on individuals is one reason why medicine and physicians exist in the first place. The main goals of medical ethics are to improve the standard of care by identifying, analyzing, and attempting to resolve ethical problems that arise in medical practice.

Organizations that lack adequate role-modeling have resulted in a lack of ethical concern for patients, inadequate monitoring of institutional ethics, and a lack of improvement in patient care resulting in deteriorating outcomes of health care. This chapter discusses ethical and legal aspects based on generally accepted principles, including cardiology-related emerging issues for developing appropriate patient care. In addition, the educational aspects related to law and ethics are briefly highlighted.

20.2 HEALTH CARE DELIVERY

Health care delivery has to be tailored with regard to recipients’ status such as attitude, knowledge, beliefs, understanding, social system position, resources,
culture, views, religious sentiments, and so on. Thus, the influencing factors for delivery of services are status and the channel adopted by the health care team. The quality of care and the quality of caring are integrated with each other in many ways.

Medicine has to be practiced by knowledgeable, competent, and compassionate physicians who have high-quality therapeutic and healing relationships with patients and their families or caregivers in the setting of a safe and efficient health care system.\textsuperscript{11} With good documentation, legal issues are less likely to occur. Analyzing the existing status of health care delivery, the Supreme Court of India has stated that doctors, hospitals, nursing homes, and other connected health care establishments are to be dealt with strictly if found to be negligent. Patients, irrespective of their social, cultural, and economic background, are entitled to be handled with dignity.

### 20.3 PHYSICIAN BEHAVIOR

Seven ideal physician behaviors were identified by Bendapudi et al.:\textsuperscript{12} physicians should be confident, empathetic, humane, personal, forthright, respectful, and thorough. These seven ideal behaviors reflect deep-seated character traits that the physician should have, as well as more superficial behaviors or skills.\textsuperscript{11} Physicians should remember that the opposite of desired physician behavior—for example, poor service, arrogance in dismissing patients’ input, disinterest in the patient, impatience in answering a patient’s questions, and callousness in discussing the patient’s prognosis—are considered negatively by patients.\textsuperscript{12}

Pellegrino’s virtues of a good physician are benevolence, compassion, courage, fidelity to trust, intellectual honesty, prudence, and truthfulness.\textsuperscript{13} All of these behaviors are essential for delivering appropriate, effective, efficient, equitable, patient-centered, safe, and easily accessible health care.\textsuperscript{14} Ayurveda, one of the ancient systems of medicine in India, insists on medical ethics; doctor–patient relationships; and the qualities of teacher, physician, and student. The cornerstones of medical ethics in Ayurveda medicine are compassion, integrity, respect, honesty, courage, and conscientiousness.\textsuperscript{15} Ayurveda’s paternal beneficence is different from modern medical ethics.

Individual factors that impair the decision-making process and their failure to maintain technical competency, such as health status, stress, alcohol, and drugs, may be seen in some physicians. A number of people in India believe that doctors are negligent, not courteous enough, not easily accessible, and prescribe unnecessary investigations and drugs;\textsuperscript{16} they attribute medical negligence to lack of knowledge on the part of doctors. Despite this, many cases go unnoticed and very few come to consumer courts. Doctors have long been portrayed as wise and dedicated healers; however, this positive image has been in decline since 1970. Recent movies have portrayed doctors as masters, commanders, greedy, egotistical, uncaring, and unethical.\textsuperscript{17,18} Complaint letters about physicians often relate to their inappropriate attitude, lack of satisfaction,
noncompliance with patients’ demands, incorrect diagnosis, complication(s) related to procedures, medical malpractice, and so forth. Even though many physicians recognize impairment and incompetency among coprofessionals, they generally do not bring them to the attention of the respective authorities or report them. 

20.4 MEDICAL ETHICS

Medical ethics is a dynamic field that plays an important role in cardiovascular medicine. Codes of ethics, advanced directives, informed consent, privacy rules, and disclosure of conflicts of interest have changed the practice of cardiology. Ethical issues are concerned with the ideas of right or wrong, duties or obligations, and rights or responsibilities. There are always gray areas in ethics. Ethical norms derived from various laws and federal and state constitutions (fundamental laws of nations) are related to citizens’ welfare, safety, and security; professional councils and statutory organizations that deal with practitioners, policies of professional organizations, professional standards of care, fiduciary obligations, institutional policies, and judgments delivered; and public health regulations and other laws related to patient care and the hospital environment.

20.4.1 Principles of Health Care Ethics

The fundamental principles and the expectations for ethical conduct are:

- Beneficence
- Fidelity
- Nonmaleficence
- Autonomy
- Justice
- Social interest

Codes of ethics provide a wealth of information on a variety of aspects such as virtue-based ethical decision making, professional responsibilities, counseling relationships, consulting, private practice, evaluation and assessment, research and publications, counselor education, training, and supervision. Keith-Spiegel and Tabachnick offer eight general ethical principles: respect for autonomy of others, doing no harm, benefit to others, fairness and equity, fidelity and honesty, dignity, caring, and doing one’s best.

Trust

Patients and the public trust doctors and health care systems, despite limitations. Trust has various dimensions and determinants. Developments in sociophysical scenarios, market-based diagnostics, drugs and devices, economic crises,
and the needs of providers have had an affect on systems and services. In addition to blind trust, Gopichandran described four more types of trust: calculated trust, trust but with verification, skeptical trust, and impersonal trust (with some overlapping features among them).

**Communication**

Information given to patients and/or caregivers should have certainty, clarity, and eliminate divergent meaning; whereas Komesaroff suggested that clinical communication often requires the deliberate preservation of uncertainty.

**Doctor—Patient Relationship**

The doctor—patient relationship is the cornerstone in health care. This helps with diagnosis, therapy, prevention, and compliance, as well as improvement of psychosocial quality of life and patient satisfaction. Medicolegal duties are essential components to maintain a physician—patient relationship.

### 20.4.2 Ethics Related to Medical Tourism

Web-based medical tourism facilitators are the connectors between foreign patients and host countries that identify concerns regarding the information displayed. Patients or caregivers are attracted by price comparisons, perceived quality of care, additional support services, other social websites, and patient blogs. These sites do not mention patients’ rights.

E-health is a multidisciplinary field. The facilitators of web-based services have to be educated about the ethical aspects of patient care, be prevented from exploiting patients or clients, and be required to respect privacy and confidentiality. International organizations, such as the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO), have formulated standard ethical guidelines for the quality of health information available on the Internet.

The various organizations need to focus on four basic principles of e-health information: self-regulation, evaluation of information, regulation, and awareness of users. Facilitators of medical tourism have to ensure confidentiality; disclose health regulations, ethical guidelines, and laws related to compensation; provide information on potential risks of travel, facility stays, and procedures; and divulge the correct details of hospitals and providers.

### 20.4.3 Ethics of Ubiquitous Health Care

Modern medicine is supported by advanced technologies and devices used for the purposes of diagnosis, prevention, monitoring, alleviation of symptoms, and therapy. Each hospital has a plethora of machines. Ubiquitous health care
is an emerging field of technology. It uses a variety of environmental and patient sensors and actuators to monitor and improve patients’ physical and mental conditions. Such machine-dependent health care poses challenging ethical questions related to trust, efficacy, and societal issues; longevity gaps related to economic status; and clinical problems related to failure of medical devices have led to mounting concerns in the regulatory processes. Medical, technical, and computer professionals have to collaborate to develop and deploy ubiquitous health care systems.

20.4.4 Consultation Ethics

Geppert and Shelton have described various aspects of consultation. It is a service and the professionals who provide consultation should follow certain principles and norms.

20.4.5 Wrongdoing in Medicine

DuBois et al. identified 10 environmental factors that enable wrongdoing in medical practice and research. To avoid wrongdoing, education and policy of ethics have to be strengthened.

20.4.6 Ethical Issues of Managing End-Stage Heart Failure

Health care providers face ethical, moral, psychological, and medicolegal challenges while providing care for end-stage heart failure. Although cardiac transplantation may have limitations, left ventricular assist devices are becoming a more prominent therapeutic option for some. While dealing with such cases, physicians find themselves in a peculiar situation of having a professional obligation to perform whatever is the best for the patient, but doing it in the context of shared decision making. At the same time, health care providers must refrain from doing anything that might conflict with the law or raise legal concerns.

20.4.7 Ethics Related to Futile Medical Treatment

In some clinical cases, discussion of medical futility reflects an apparent conflict between respect for patient autonomy and the preservation of ethical integrity of the medical profession. The danger of futility-based exception to informed consent includes the emergence of paternalism and physicians’ avoidance of difficult discussions with patients about dying and death. Hariharan et al. have described indifference toward ethical and legal issues among doctors and nurses, and the need for appropriate training.
20.4.8 Integration of Complementary Therapy

Integrating the use of complementary therapies in medical practice increases the physicians’ risk for license suspension or revocation.\textsuperscript{38,39} It is suggested that physicians should continue to provide conventional medical care.

20.4.9 Medical Errors

Medical errors are bound to happen. Even though they may be known, errors often do not come to light or go undocumented because of the inherent threatening attitude of the existing health care system and the possibility of self-harm. Moreover, medical errors are not discussed as a part of medical education. In most situations, nurses and paramedical professionals do not have the liberty to write medical errors in their reports and are not trained to document such incidents because they are considered suboptimal. As a result, prevalence cannot be estimated, occurrence cannot be prevented, and root cause cannot be assessed. The complexity of the current health care system contributes to various types of medication errors, leading to legal liability. Reducing such errors is an ongoing process of quality improvement, which is an essential component of clinical audits. In some cases, root cause analysis and redesigning faulty systems have reduced medication errors.\textsuperscript{40}

20.4.10 Ethical Practice in Laboratory Medicine

Medical laboratories have responsibilities to three main groups: patients, professional colleagues, and society. They are required to maintain high standards in sample collection, good laboratory practices, reporting, monitoring, maintenance of records, and confidentiality.

20.4.11 Ethics Related to Treatment

While making decisions about resuscitation, health care providers should be guided by science; individual patient or surrogate preferences; local policy and legal requirements with reference to respect for autonomy, advanced directives, living wills, patient self-determination, do not attempt resuscitation (DNAR) orders, withholding and withdrawing cardiopulmonary resuscitation (CPR), and terminating resuscitation efforts. All these should include providing emotional support to family, limitations of care and withdrawal of life-sustaining therapies, ethics of organ donation, and privacy.

20.4.12 Ethical Issues in Cardiac Surgery

Deliberations about ethical issues among cardiothoracic surgeons have gained prominence in recent years and is starting to become part of medical schools’
curriculum. A recent review described various ethical issues related to cardiac surgery in a detailed manner.\(^{41}\)

### 20.4.13 Medically Acceptable Wait Time

Wait time for access to a cardiovascular specialist’s evaluation and therapy has an impact on a vulnerable population in many ways including lawsuits. Shortage of cardiologists and demands from the community have been discussed by professional societies, universities, and health ministries.\(^{42}\)

### 20.4.14 Ethical Issues in Fetal Management

If a fetus is found to have a cardiac anomaly, the ethical principle of autonomy creates a responsibility for the physician to help the pregnant woman make an informed decision based on her values and aspirations. A decision to terminate is partly a medical matter and partly a personal decision bound by legal, cultural, and religious constraints.\(^{43}\)

### 20.4.15 Do No (Financial) Harm

“Do no harm” is an established mantra of medical ethics and the profession. In the modern era, medical bills are escalating and are the leading cause of financial harm.\(^{44}\) Physicians, while providing patient-centered care, should also consider patients’ financial well-being.\(^{45}\) They should understand financial ramifications, provide appropriate care, and optimize care plans for individual patients considering their socioeconomic status.

### 20.4.16 Shift from Individual Autonomy

In order to achieve patient-centered care, family members and/or caregivers need precedent education and assistance. This will entail a fundamental shift from individual autonomy to family- and caregiver-centered care.\(^{46}\)

### 20.4.17 Ward Rounds

Ward rounds provide a benefit to patients that is safe, effective, and efficient. In addition, rounds can lead to staff and patient satisfaction.\(^{47}\) When various levels of health care providers see and talk to patients, they gain confidence and are more satisfied. In addition, ward rounds involve teamwork, where senior and junior doctors, medical students, nurses, and paramedical professionals share patient information and gain knowledge.
20.4.18 Ethics Related to Health and the Media

Standard ethical guidelines need to be practiced while disseminating information about health, disease, institutions, and physicians to the media. The media (i.e., print, television, Internet) has become a powerful source for sharing information and knowledge.\textsuperscript{48} Issues related to ethics and the media, including showing patients in news stories or taking pictures of them, have to be evaluated, and students of health sciences and practitioners/physicians should be aware of these issues. The importance of the media was revealed during the epidemics of severe acute respiratory syndrome (SARS) and the H1N1 influenza infection. It has been suggested that the media become a partner in health care delivery to carry messages quickly to the population, to enforce prevention or therapeutic strategies,\textsuperscript{49} and to protect communities from hazards.\textsuperscript{50}

20.4.19 Ethics for Medical Education

The medical profession is considered a noble profession. Ethics is important for the correct conduct of the professionals and practitioners. There are two levels in a teacher’s ethics: legal and/or administrative and personal. Medical educators have various roles including teacher, manager, administrator, researcher, and physician, and all roles are governed by and require a code of ethics.\textsuperscript{51}

20.4.20 Involving Patients in Medical Education

In clinical teaching, patients are brought to a consultation room or students are taken to the patient for bedside instruction. In developing countries, many times ethical principles are violated or not followed when patients are involved in medical education.\textsuperscript{52} Principles of ethics have to be discussed at every stage of clinical teaching.

20.4.21 Research and Publication Ethics

Like the fact that human beings need oxygen to breathe, science needs research to live and progress. Thus, research is an essential component in the science. Publications help exchange and share knowledge for the betterment and advancement of medicine. Therefore, authors are expected to follow standard ethical guidelines when submitting research for publication.\textsuperscript{53}

20.4.22 Ethics Related to Patients with Heart Disease

Hall et al.\textsuperscript{54} have noted that cardiac patients should be assessed by cardiologists as a matter of course. The authors suggested that health care providers listen to patients’ various needs; provide access to information technology (IT) for audit, clinical governance, and continuous professional development (CPD); and collect
valuable outcome data. The authors, while discussing human rights, stated that cardiac cases should not be delayed when starting treatment or denied ethics for want of resources because of an unpredictable response from the illness.\textsuperscript{54}

### 20.4.23 Defensive Medicine and Consumer-Driven Health Care

Defensive medicine is defined as the ordering of tests, procedures, and visits and/or referrals, or avoidance of high-risk patients or procedures, primarily to reduce malpractice liability. A study from Israel revealed that defensive medicine is prevalent, especially among surgical specialties, and more so among those exposed to lawsuits.\textsuperscript{55} Studies have revealed that defensive medicine is a well-known practice in industrialized countries.

Emergency medicine, general surgery, neurosurgery, obstetrics, gynecology, orthopedic surgery, and radiology specialists were common in defensive medicine and were affected more by liability cases.\textsuperscript{56} The influencing factors for defensive medical practice are increasing demands of the patients, lack of resources, work and patient loads, deviation from standard guidelines, and increasing lawsuits and compensation amounts. Measures to reduce lawsuits and complaints are improving the quality of care, clinical audits, anonymous disclosure of medical mistakes, resources, practicing standard guidelines, lawsuit immunity, and no-fault compensation.

Current public reports compare health care providers in terms of quality or cost to help consumers, who in turn decide where and from whom to seek care.\textsuperscript{57} In view of the changing trends of consumers, health care providers need to become accustomed to patient empowerment and meet their expectations. The public expects standard guidelines for treatment; however, they too have limitations,\textsuperscript{58} and conflict of interest (CoI) is prevalent in the ones related to cardiology.\textsuperscript{59}

### 20.5 LEGAL ISSUES

Sophistication of medical practice, increasing costs of health care, involvement of insurance systems, increased awareness and high expectations from the community, and increased participation of media have enhanced society’s attitude toward claiming compensation and acquisition of health care delivery. This section outlines the various ways by which hospitals and health care providers can minimize their exposure to legal liability or consequences.

#### 20.5.1 Sources of Legal Obligations

There are numerous sources for obligation in emergencies and health care providers should identify legal issues and adopt a risk management approach,\textsuperscript{60} including characterizing the hazards, establishing a community profile, determining vulnerability, analyzing risk, and identifying and
evaluating the management plan. An alternative way to avoid legal liability is to use the PPRR (prevention, preparedness, response, and recovery) framework.

20.5.2 Law and the Legal System

Laws include federal and state constitutions, statutes, and administrative and judicial decisions, which may vary from country to country and/or state to state; thus, a legal cause of action may be created by a constitutional right, by a statute, or by a common law. A cause of action consists of several distinct elements; however, the following must exist before there is legal liability:

- Plaintiff must have an interest that is protected by law
- There must be a legal duty
- A breach of duty by the defendant must be provable
- An injury must be shown as damage to the protected party
- It must be proved that the breach of a law caused injury

20.5.3 Negligence

Negligence is the most common allegation (cause of action) in medical practice cases. It is legally defined as the omission of something that a reasonable person, guided by ordinary considerations of someone who regulates human affairs, would do; or the doing of something that a reasonable and prudent person would not do. Therefore, negligence is a violation of the duty to use care. It arises when injury results from the failure of the wrongdoer (“tortfeasor”) to exercise due care. The four elements required to establish a prima facie case for negligence are duty, breach, causation, and compensable injury.

20.5.4 Malpractice

Malpractice is defined as a tort or civil wrong committed by a professional acting in his or her professional capacity. The term malpractice refers to any misconduct that encompasses an unreasonable lack of skill or unfaithfulness in carrying out professional or fiduciary duties. Malpractice law is a part of tort or personal injury law. The three goals of malpractice litigation are to deter unsafe practices, to compensate persons injured through negligence, and to exact corrective justice.

Plaintiffs’ legal theories or causes of action against a physician are ethical negligence, wrongful death, loss of a chance of recovery or survival, battery and assault, lack of informed consent, abandonment, breach of privacy and confidentiality, product liability because of drugs and medical devices, vicarious responsibility for the acts of others, negligent referral, false imprisonment, defamation, failure to warn or control, negligent infliction of emotional
distress, outrage, failure to report, fraud or misrepresentation (deceit), and loss of consortium.\textsuperscript{61}

\textbf{20.5.5 Competency}

The issue of determining patient competence for medical decision making is often difficult. No absolute definition exists.\textsuperscript{62} Competency is essentially the ability of a person to make a decision, and it is where understanding, appreciation, nationality, and religion begin.\textsuperscript{62}

\textbf{20.5.6 Duties of Prescribers}

The prescriber exercises clinical skill in diagnosing a condition and determines which drug is indicated and in what dose. Also, the prescriber has to provide sufficient information to the patient so as to make an informed decision whether or not to take the drug in the light of any possible adverse effects or risks that may be associated with the choice.\textsuperscript{63} Illegible prescriptions have been a source of legal liability for both pharmacists and prescribers. Therefore, prescribers should respond to queries from pharmacists to avoid the possibility of injury to the patient and expensive litigation for all concerned. Patients may be motivated to follow the directions on product information (PI). A consumers’ movement view is that an off-label prescription indicates it as experimental; under such circumstances, the prescriber has to provide complete information to obtain the patients valid informed consent.\textsuperscript{64}

Prescribers should focus on evidence and drug quality, as opposed to commercial influences. Both prescribers and pharmaceutical companies need ethical regulation.\textsuperscript{65} The practice of gifts from pharmaceutical companies to doctors alters the physicians’ decision in prescribing the drug, which may be expensive and in turn could cause poor patient compliance.\textsuperscript{65} Such practice should not be encouraged. Pharmaceutical companies should disclose payments made to doctors above a certain value in their accounts, as is already practiced in some countries. In the United States, according to federal law, drug companies must disclose payments made over a certain value to physicians for research and other miscellaneous expenses.\textsuperscript{65}

\textbf{20.5.7 Legal Action against Health Care Providers}

A health care provider is likely to be charged for civil actions against injuries resulting from lack of informed consent and standard care. Medical treatment and malpractice laws are specific to each state and may vary with different countries.
**Informed Consent**

Ethical and legal standards require a health care provider to obtain informed consent (IC) before delivering care. If the patient cannot provide it, a legally authorized surrogate decision maker may do so. In an emergency, when the patient is not legally competent to give IC and no surrogate decision maker is readily available, the law implies consent on behalf of the patient. Information should be conveyed in a language and at a level that the patient can understand, and consent should be obtained for diagnostic tests, treatment’s nature and character, anticipated results, and risks and benefits of treatment (or no treatment), along with other alternative options if available. The informed consent must be voluntary.

The physician is responsible for obtaining IC and delineating the potential risks, benefits, and alternatives. Physicians must be transparent for all potential ethical or financial conflicts concerning therapies and various other matters related to them or the devices employed in patient care. Patients’ reaction to confidentiality, liability, and the financial aspects of IC in cardiology research have been described by Fortune-Greeley et al. In a 2012 study, informed consent forms for cardiology practice were found to be suboptimal and lacking in clarity.

The number of patients coming to the emergency department (ED) for diversities of toxicological emergencies is on the rise. Each patient requires immediate care and yet is unable to give consent due to impaired consciousness—that is, prevents the patient from making informed decisions. Some of the challenges faced by emergency physicians are acute organic impairment manifested by confusion, irrational thoughts, or dangerous behavior at times. They should familiarize themselves with relevant laws, which vary from state to state and country to country, and carry out immediate management to avoid liability for negligence and abandonment.

There has been much discussion about IC and its types. Medical ethicists claim that informed consent is valuable because it supports individual autonomy. In addition, it provides an assurance that patients and others are neither deceived nor coerced. In real clinical scenarios, there are variations among patients. Since there are many distinct conceptions of individual autonomy, ethical importance varies. Consent forms should be designed to give patients and others control over the amount of information they receive and the opportunity to rescind consent given already. Limitations of informed consent are getting informed consent from the young, very ill, mentally impaired, or unconscious patients; or patients brought to the ED. Other limitations are non-applicability for public health policies, access to a patient’s personal information by third parties, and duress or constraints experienced by patients.

**Failure to Follow the Standard of Care**

A patient has to prove the provider’s failure to follow the accepted standard of care. There are various sources for standard of care. Many states apply
different standards to specialists and practitioners with accommodations for practice limitations such as availability of medical facilities, services, devices, and the like. Common ethical issues are related to medical decision making and good patient—physician communication.

Laws and regulations on surrogate decision making are slowly evolving due to societal changes. It is highly recommended that readers become familiar with the various laws and regulations related to decision making according to their country or state. Other areas of ethics with regard to treatment are advanced directives, futile resuscitation, withdrawal of treatment, missed diagnosis, medical issues, incorrect procedures or drugs, prescription-related matters, adverse effects to drugs, failure to screen family members, withholding diagnosis and information, organ transplantation or harvesting, and breach of confidentiality.

20.5.8 Vicarious Liability

Hospital authorities are vicariously liable for the unlawful act of physicians or nurses, and/or others employed by them when such acts occur during the course and scope of individuals’ work.

20.5.9 Patient’s Bill of Rights

Doctors are often alarmed by the patient’s bill of rights but should remember it is for everyone, including doctors. Familiarizing oneself with the patient’s bill of rights is especially important in this era of medical tourism. Care providers should disclose patients’ rights to their clients before entering a contract. Benefits of a patient’s bill of rights are:

- Improved awareness within the health care system
- Increased expectations of the patients
- Empowerment of patients
- Changes and improvement in the attitude of health care practitioners, professionals, and providers
- Partnership between consumers and providers
- Improvement in the quality of health care

A bill of rights should be revised or reconsidered periodically so as to benefit the patients and address the concerns of the health care system.

20.5.10 Abuse of Power

Physicians have the privilege of making decisions to investigate, treat, or refer cases. Decisions are influenced by clinical, psychological, economic, and other issues. During clinical practice, however, doctors may be at risk of abusing this privilege. Similarly, in recommending leave on medical grounds, some
doctors are likely to overuse their privilege for want of definitive guidelines. Granting medical leave has an impact on productivity; thus, there is a need to develop standard guidelines for recommending a medical leave.

**Doctor and Patient Realization of Risk**

Both doctors and patients should realize that sickness, pain, and death are part of life and medicine, that diagnostics and therapy have limitations, and that predictions of clinical course and outcome may not always be certain. All these may become less or averted once personalized medicine becomes a reality. Doctors and patients have to accept the risk of developing a drug reaction (i.e., drug reactions can neither be predicted nor prevented on all occasions) and treatment complications. Good communication and understanding of all these aspects is a part of ethics and, if well understood, litigations are less likely to arise.

**20.6 EDUCATION AND TRAINING**

On most occasions, health care professionals are unaware of the importance of ethical practice. It needs to be introduced in education curricula, and training on clinical ethics in health care settings is also beneficial. Medical schools organize clinico-pathological conferences (CPC) where students and faculty interact with each other, but discussions on judgments related to health care or liability cases and ethics are not often presented. Interactive programs in medical schools and clinical practices about such issues will help students and physicians understand not only the intricacies of laws related to health care and the shortcomings of health professionals and health systems, but also strengthen their understanding of ethics and laws, improve their practice and standard of care, and minimize litigation issues.

**20.6.1 Teaching Ethics and Laws in Medical Schools**

Medical students are trained and exposed to CPCs regularly during their studies. They are confident about substantiating their statements with evidence. However, most students do not have the confidence to do a clinical audit, to find deficiencies in medical records, to correlate the laws related to patient care, and/or to provide legal support to patients. This is because knowledge about the legal issues is suboptimal among medical teachers, and legal and ethical aspects are not discussed during regular ward rounds or grandrounds, nor are they incorporated into lecture classes. Anything that is not learned in medical school is less likely to be remembered and practiced or inculcated. The University of Iowa College of Medicine is among a relative few to offer separate courses in ethics and law as part of their curriculum.
20.6.2 Continuing Medical Education

The European Society of Cardiology (ESC) has made recommendations about how to minimize bias in all scientific communications and continuing medical education (CME), and how to ensure proper ethical standards and transparency between the medical profession and industry.\textsuperscript{75,76} Medical education and training do not focus on the intricacies and importance of consultation aspects and, thus, these have to be incorporated into the curriculum. Suitable modules have to be prepared for training doctors on the principles of consultation. Current medical curricula in India lacks ethics\textsuperscript{77} and medical humanities; training programs to acquire such skills were proposed by the Medical Council of India,\textsuperscript{78} but implementing them awaits permission from the Indian government.

Law and ethics support health care professionals and services rendered.\textsuperscript{79} The United Kingdom’s National Health Service (NHS) has introduced programs to teach and train health care professionals about law, ethics, education, and development (LEED) based on surveys. A central thrust of the program was the initiation of an “Introduction to Health Care Law and Ethics” study day.\textsuperscript{79} In this survey, 74 to 100\% of participants rated the educational value as excellent. Although the program has now been stopped, there is a need for all to have access to law and ethics. By and large, there is no dispute for dissemination of knowledge on ethics and law to health professionals.

20.6.3 A Model Curriculum for Legal Medicine and Medical Ethics

Some of the subjects that are included in teaching and training for legal medicine and medical ethics are medical humanities, public health policies, the business aspects of medicine, forensic sciences, end-of-life issues, how to care of special patients, the liability of specialties, and medical liability. Also such a curriculum should cover hospitals’ reputation in medical practice, nursing facilities, managed care organizations, laws, courts and judicial processes, consumer protection acts, human rights, state medical boards, hospital ethics committees, and medical examiners.

Cardiovascular training should recognize and address ethical issues, the rational use of resources, and conflicts related to end-of-life care. A cardiovascular advance directive should address the deactivation of a pacemaker, use of an implantable cardioverter defibrillator (ICD), or a left ventricular assist device (LVAD). In addition, cardiovascular clinicians should understand ethical dynamics and equip trainees with the tools of ethical reasoning because the complexity of the specialty continues to increase.\textsuperscript{80—86} Medical students and physicians-in-training should be trained in the various components of medical ethics—for example, definition, approaches, perspectives, ethics of individuals, ethics of human life, ethics related to family and society, ethics related to death and dying, research ethics, ethical work-up of
cases, doctor—patient relationships, doctor—doctor relationships, pharmaceutical ethics, transplant ethics, resource allocation, end-of-life ethics, truth and confidentiality, decision making, teamwork, social responsibility, and so on.

20.6.4 Early Exposure to Ethics

Medical students are exposed to the intricacies and interconnections between physiological systems and their influence on living organisms. There are also opportunities available to introduce and discuss ethics and ethical issues and reinforce ethical principles. Introduction of ethics in physiology has led to a greater awareness of the importance of ethical issues and are likely to be more widely practiced in clinical practices too.

20.6.5 Medicolegal Guidelines

Even though doctors make appropriate efforts to treat patients, they have to be trained and retrained about proper documentation from the point of view of litigation; encouraged to record dying declarations and obtain valid consents; and trained on the preservation and confidentiality of medical records, on the avoidance of hiding facts, and on adherence to standard guidelines for therapy. The latter includes selection of the therapeutic agents, methods, and/or procedures and substantiating written statements if there are any deviations. In addition, guidance is needed for the reporting of illnesses to public health authorities as per the regulations of the county or state and hospitals.

20.6.6 Clinical Audit

A clinical audit is an essential component of clinical governance. It considers procedures adopted to diagnose, methods used to deliver health care and treatment, utilization of resources, and the effect of outcome along with quality of life of the patient. Principles for the best practice in clinical audit, published by the National Institute for Health and Clinical Excellence (NICE), defines it as a quality improvement process that seeks to improve patient care and outcomes through systemic care delivered against explicit criteria and the implementation of change.

Even though the terms medical audit and clinical audit are used interchangeably, clinical audit has multiple components related to patients, education and training, health care delivery, resources for health, working relationships, and so on. In addition, a clinical audit helps when listening to patients; understanding patients’ expectations; deals with evidence-based practice; assists in the development of local guidelines or protocols; minimizes error or harm to patients; and reduces incidents, complaints, and claims. Because a clinical audit involves patients and patient-related matters, confidentiality of information has to be
adhered to strictly. For the review of case notes during a clinical audit, there is no need for informed consent from patients as long as confidentiality and anonymity are preserved.  

20.6.7 Teaching and Assessing Medical Ethics

Medical ethics has been incorporated into medical education and training. However, the shortfall in ethics core competencies does not preclude graduation. There is a need for greater integration of ethics in theory and practice. Major concerns are how to make a medical faculty impart medical ethics to students of health care sciences. The “Cardiology Ethics Curriculum” at the University of Toronto is a useful resource. Ethical components are rarely discussed in during ward rounds. Teaching ethics should be incorporated into all clinically oriented teaching and training activities. Students can also learn ethics through role models and interaction with patients, instead of formal lectures. Because medicine and ethics are inseparable, teaching ethics at the bedside becomes essential but is seldom done. There is a need to introduce bioethics as part of the curriculum at all health science education institutions.

The complexity of the technology involved in making a diagnosis and therapy requires a careful search for the right answer under some very difficult situations. Training on descriptive bioethics using various modern medical education technologies and discussion with fellow doctors, hospital administrators, religious leaders, and social scientists in difficult situations, can help to make policy decisions amicable to the patient, family, and society. Achievements in medical practice and health care delivery depend on the status of the medical education system, the nature of medical manpower, economic resources, the health care system, and, importantly, medicolegal law. The quality of medical manpower and medical services are determined by policy, findings, regulatory mechanisms, professional organizations, direction from judiciary, and expectations and participation of the community.

A common difficulty in the current medical education system is that it fails to inculcate appropriate skills and competencies to recognize and tackle ethical issues among the learners. Although developing an ethics-based medical education system is a challenging task, we have to take initiatives to deal with a variety of issues.

Prevention

A. Knowledge in medicine and timely application in a given situation to assess the case at the bedside meticulously with empathy; analysis of clinical issues and challenges, and differentiating one from another with or without the help of laboratory data; application of appropriate specific and nonspecific measures to alleviate the symptoms or to treat cases with currently available guidelines; acceptance of limitations of knowledge and skills,
resources, and constraints; arrangement for referral or consultation; provision of follow-up care, rehabilitation services, or welfare program depending on the case; proper documentation, adequate informed consent, continuous monitoring to strengthen physician–patient relationship, patient satisfaction, and quality of life, thereby avoiding any conflicts or liability issues.

B. The attitude of health care professionals toward the patients shall be:
   1. Receive them with care and concern
   2. Respond with empathy
   3. Realize the underlying clinical problem(s) and manage with appropriate measures
   4. Review the clinical course, therapeutic strategies, and outcome
   5. Revise the plan and management with shared decision
   6. Seek further help, if needed

C. Cardiologists should be informed to establish the kind of actions, communication skills, and empathy that are required to build a stronger patient–health care professional relationship, which improves prognosis, treatment efficacy, and therapeutic adhesion.97

D. Cardiac report cards should be developed that incorporate an ethical framework, which can identify points of ethical concern for practitioners, patients, policymakers, and researchers98

E. The integrity and behavior of an individual physician plays a major role in the prevention of liability cases. Professional associations play a major role in the regular monitoring process and for initiating self-regulation of professionals.

F. Doctors involved in handling insured patients are encouraged to consult Booth, 2008,99 which has extensive information on prevention. Also, physicians are encouraged to familiarize themselves with local guidelines because policies and practices of health care insurers are extremely varied.

G. The role of community participation and utilization of existing laws and regulations in India toward clinical trials have alerted the highest health care bodies in the country, such as the Ministry of Health and Family Welfare (MOHFW), Central Drugs Standards Control Organization (CDSCO), and policymakers, to introduce new regulations on compensation for injury and death occurring during drug trials.100

H. The Clinical Establishment Act101 of India, if implemented, will improve the dignity of patients and ensure safe services.

I. To overcome the legal issues, one has to follow ethics and maintain professionalism and team spirit at all times. Respect, dedication, sincerity, compassion, good communication skills, prudence, meticulous documentation, and acknowledging the limitations of one’s abilities help avoid legal liability.

J. In India, the Supreme Court included the health profession under the 1986 Consumer Protection Act (CPA) of India [Supreme Court judgment AIR 1995 SC 550, dated 13.11.1995. New Delhi, India]. As a result, doctors can be charged for medical negligence liability under CPA.102

K. Responsibilities of the health care institutions: Health care institutions have to provide a written notice of their privacy policy to all those who seek medical care for the first time. Patients must be informed of how the institution may use and disclose information. The written notice must describe
patient’s rights, including the right to access their medical information and their right to provide feedback or complaint, if they believe their rights were violated. The notice shall be in plain language and presented in an understandable manner. An acknowledgment of receipt of the information notice must be obtained from the patient. The institution shall have a close working relationship among medical personnel, legal, and risk management team. The team, through interaction on case by case basis, can acquire a wealth of information, learn, and meet the needs of clinical dilemma, which are evolving constantly. Such interactions enhance health care and ensure patient safety, and thereby establish a high standard of care. Also, the institution shall ensure quality assurance, organize risk management programs, and conduct routine audits or monitoring as suggested by a specialist’s team. Laws generally require that therapeutic interventions be done in a reasonable and medically approved manner, preferably based on clinical evidence or standard guidelines. Medical staff dealing with cases should remember that the issues raised by any one case are complex and application in a real situation is difficult. Hence, staff should review the hospital counsel and the local laws and regulations pertaining to these issues.

L. Medical records: Medical personnel should be trained and motivated for proper documentation, adherence to risk management principles, and entry of every aspect related to the case in the respective medical record. The physician is required to write a medical record that will support the basis for the appropriate medical judgment made. The medical record should reveal supporting clinical data or facts, the patient’s history available at that time, hemodynamic status, physical examination, investigation reports, and treatment plans administered. One must remember that hospital records are prima facie evidence. Therefore physicians who do not record supporting clinical data and history deprive themselves of a strong “medical judgment defense.” Moreover, inappropriate entries or markings on the medical record can weaken the defense in a liability case.

If any corrections are required in the medical record, the preferable method is to draw a single line over the word or value to be changed; and at the place where such correction is made, initials or signature should be affixed. However, total obliteration of a number or word may indicate that obliteration was done intentionally. Quality-assurance reviews of records of EDs often reveal inadequate charting by physicians and nurses. A lapse of documentation of patient’s clinical condition for 4 hours or more after initial physician and nursing assessment will be utilized by the plaintiffs attorney in a lawsuit to develop the theory that no care was given. The uncooperative acts of the patient and the difficulties encountered in providing care to the patient because of his or her actions should be recorded. Poorly written physicians’ notes may become an issue in a medical malpractice action and considered a less-than-caring attitude by the doctor. Descriptions of a patient’s behavior and lifestyles should depict compassion and a professional manner. Health care institutions and cardiovascular physicians should realize consumer rights and responsibilities such as information disclosure, choice of providers and plans, access to emergency services, participation in a treatment discussion,
respect and nondiscrimination, confidentiality of health information, and complaints and appeals.83

M. Incentives and ethics: Incentives, in different forms, have been introduced for various services and are not accessible in health care delivery.105 Incentive mechanisms are based on four types of motives: traditional, self-interest, affective, and shared purposes. Financial incentives have helped to achieve the quality or efficiency of related targets but have potential adverse consequences including conflicts of interest that threaten patient—physician trust. The ethical allegations, implications for effectiveness, and mechanisms of different motives were highlighted. Incentive schemes based on a robust sense of shared purposes protect and promote physicians’ sense of moral responsibilities and ethical standards. These also enable physicians to take ownership of it rather than make them feel it is imposed on them.105

N. Patient-centered specialty practice: As a part of a new phase of health care delivery systems, the National Committee for Quality Assurance (NCQA) launched patient-centered specialty practice (PCSP) in 2013. The objectives of the committee are to reinforce care coordination, improve access to specialty care, reduce the use of unnecessary or duplicate tests, enhance communication, and assess and improve performance.106

O. Provision of safe prescriptions is already included in the curriculum of health sciences. However, prescription errors remain a significant cause of patient harm. Lum et al.107 identified 12 core competencies for safe prescribing and listed them under 4 stages: information-gathering, decision making, communication and decisions, and monitoring and review.

- Overall, medical students and physicians should be trained and motivated to maintain:
  - Physician—patient relationship on all aspects of patient care
  - Holistic approach
  - Empathy
  - Respect for patient autonomy
  - Involvement of patients or, where appropriate, family members or caregivers as partners in therapeutic and management decisions
  - Respect for patient culture, values, views, and beliefs or religious sentiments
  - Consideration of patient’s views on the use of alternative treatment options
  - Nonjudgmental attitude in all aspects of work
  - Engagement in reflective practice
  - Clinical audit

Delay in diagnostic investigations, the nonavailability of interventional procedures, recurrent and repeated system failures, and so on, are real aspects of all our daily lives, yet rarely are considered in mitigation. Careful documentation of these failures is paramount, if we need to defend ourselves against a system that seeks criminal prosecution or compensation. A legal decision for violation of ethics may lead to loss of status, career, and livelihood.
20.7 FUTURE DIRECTIONS

It is worth studying the patterns and prevalence of defensive medicine and the status of lawsuits in different countries to find any economical impacts and adverse effects. Patterns of malpractice insurance systems adopted in various countries and the compensation paid to patients should be analyzed and the information shared among health care professionals, community members, and payers, so as to design modalities to reduce expenses.

Periodic analyses of physician behaviors and attitudes, along with health care utilization and lawsuits, are likely to help professional organizations and health science educators introduce teaching and training modules for reduction in malpractice lawsuits. The consequences of wait time for health care services in terms of quality of life and health care economics should be studied for the effective introduction of remedial measures.

The attitude of physicians and their beliefs, preparedness, and experiences related to impaired and incompetent colleagues should be explored, as well as suggestions to overcome them. Issues related to devices, drugs, and diagnoses with reference to ethical and legal aspects and alternatives for better treatment of the patient should be analyzed. Periodical analyses of judgments related to health care issues, health care professionals, and health services at national and international levels, as well as identification of the causes, to find methods to avert them can be undertaken at educational and industrial levels.

The capacity of medical students and practitioners to get informed consent should be evaluated and suitable measures introduced to teach and train them. Analyses of curriculum and methods of teaching and training should be undertaken, and medical students should be assessed on their knowledge of ethics and laws. A common curriculum should be introduced so that medical students can be trained uniformly to deliver health care effectively and as expected. Moreover, such a curriculum will help patients and practitioners, as patients start moving between countries for medical treatment (medical tourism).

The current status of consultation and its impact on the part of referring doctors and their patients have to be studied to find lacunae. Suitable modules should be prepared for training doctors on consultation. There are inter- and intracountry variations in one or more components of bioethics, thus the boundaries are disputable. Disagreements about the relationship between ethics and law should be addressed.

Future directions in therapeutics should focus on the role of pluripotent stem cells in cardiotoxicity, the feasibility implications of personalizing health care, and the assessment of myocardial neuronal function. Health science research explores basics, epidemiology, risk, prevention, diagnostics and management, financial burdens of disease, and behavioral aspects. Each component of health science should focus on ethical aspects before asking for funding. Cardiovascular research should produce guidelines on management of end-of-life care, palliative care, and support for patients’ decisions to forgo treatment.
Cardiovascular physicians should prepare and produce modules to facilitate the patient and faculty decision-making process about cardiovascular health.

Managed care organizations (MCO) and cardiovascular physicians should plan and develop guidelines to handle ethical issues or problems related to MCO and standard of ethics for hospital administrators and all others involved directly or indirectly with patient care. Protocols and algorithms need to be developed to curtail inappropriate prescribing, unnecessary testing, overuse of technologies, diversion of scarce resources, and nonrecognition of complications.

20.8 CONCLUSION

The public has realized that “doctors are not always to be trusted, as they have fallen off their pedestal.” Doctors, therefore, have to remain up to date and demonstrate their continuing competency. Currently the duties and responsibilities of doctors have been defined by medical councils belonging to the individual country where they practice. As medical tourism has developed and patients are moving from one country to another for treatment, there is a need to develop an international norm to overcome inter- and intracountry variations.

Cardiovascular care is increasingly complicated, device-oriented, and expensive, and it requires striking a balance for quality of life and longevity. The modern cardiovascular specialist has to explain these spectra, considering individual patients’ wishes and best interests, the maleficence of side effects, and the impact of therapeutic interventions in the larger social context. To achieve these things, physicians should acquire skills in the art of medicine and interact with patients and caregivers with empathy, astute observations, accurate interpretation of clinical and laboratory data, and application of up-to-date knowledge with evidence and ethics. This can strengthen insight into disease and suffering and provide a means to diagnose, treat, and prevent disease; if followed meticulously and documented sincerely, legal liability is less likely to develop.

Treatment decisions, in general, should be based on a profound respect for the patient’s autonomy, balanced by an appreciation of what may be in the patient’s best interest. Decision making involves a wide array of personal, professional, institutional, spiritual, and social values. In routine practice, clinical management decisions should be coupled with outcome analyses and guide physicians’ approach to best address the needs and expectations of patients. To improve the quality of the physician—patient encounter, we need to develop formal and informal curricula at medical institutions on communication skills and ethics.

Key Learning Points

- Illness remains universal; however, human expectations and experience may vary personally and geographically.
• Principles of ethics and legal aspects have to be incorporated into health science education and discussed at every stage of clinical teaching.
• Ethics and legal aspects related to emerging areas of health care, such as medical tourism, ubiquitous health care, consumer-driven health care, integration of complementary therapy, and so on, need to be addressed.
• Curriculum about medical ethics should be included in all aspects of medical education and training, including continuing education. Such measures should reduce the possibilities of medical liability cases.

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