
Harrison's Principles of Internal Medicine, 21e >

Chapter 11: Ethical Issues in Clinical Medicine

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INTRODUCTION

Physicians face novel ethical dilemmas that can be perplexing and emotionally draining. For example, telemedicine, artificial intelligence, handheld personal devices, and learning health care systems all hold the promise of more coordinated and comprehensive care, but also raise concerns about confidentiality, the doctor–patient relationship, and responsibility. This chapter presents approaches and principles that physicians can use to address important vexing ethical issues they encounter in their work. Physicians make ethical judgments about clinical situations every day. They should prepare for lifelong learning about ethical issues so they can respond appropriately. Traditional professional codes and ethical principles provide instructive guidance for physicians but need to be interpreted and applied to each situation. When facing or struggling with a challenging ethical issue, physicians may need to reevaluate their basic convictions, tolerate uncertainty, and maintain their integrity while respecting the opinions of others. Physicians should articulate their concerns and reasoning, discuss and listen to the views of others involved in the case, and utilize available resources, including other health care team members, palliative care, social work, and spiritual care. Moreover, ethics consultation services or a hospital ethics committee can help to clarify issues and identify strategies for resolution, including improving communication and dealing with strong or conflicting emotions. Through these efforts, physicians can gain deeper insight into the ethical issues they face and usually reach mutually acceptable resolutions to complex problems.

APPROACHES TO ETHICAL PROBLEMS

Several approaches are useful for resolving ethical issues, including approaches based on ethical principles, virtue ethics, professional oaths, and personal values. These various sources of guidance may seem to conflict in a particular case, leaving the physician in a quandary. In a diverse society, different individuals may turn to different sources of moral guidance. In addition, general moral precepts often need to be interpreted and applied to a particular clinical situation.

ETHICAL PRINCIPLES

Ethical principles can serve as general guidelines to help physicians determine the right thing to do.

Respecting Patients

Physicians should always treat patients with respect, which entails understanding patients' goals, providing information, communicating effectively, obtaining informed and voluntary consent, respecting informed refusals, and protecting confidentiality. Different clinical goals and approaches are often feasible, and interventions can result in both benefit and harm. Individuals differ in how they value health and medical care and how they weigh the benefits and risks of medical interventions. Generally, physicians should respect patients' values and informed choices. Treating patients with respect is especially important when patients are responding to experiences of, or fears about, disrespect and discrimination.

GOALS AND TREATMENT DECISIONS

Physicians should provide relevant and accurate information for patients about diagnoses, current clinical circumstances, expected future course, prognosis, treatment options, and uncertainties, and discuss patients' goals of care. Physicians may be tempted to withhold a serious diagnosis, misrepresent it by using ambiguous terms, or limit discussions of prognosis or risks for fear that patients will become anxious or depressed. Providing honest information about clinical situations promotes patients' autonomy and trust as well as sound communication with patients and colleagues. When physicians have to share bad news with patients, they should adjust the pace of disclosure, offer empathy and hope, provide emotional support, and call on other resources such as spiritual care or social work to help patients cope. Some patients may choose not to receive such information or

may ask surrogates to make decisions on their behalf, as is common with serious diagnoses in some traditional cultures.

SHARED DECISION-MAKING AND OBTAINING INFORMED CONSENT

Physicians should engage their patients in shared decision-making about their health and their care, whenever appropriate. Physicians should discuss with patients the nature, risks, and benefits of proposed care; any alternative; and the likely consequences of each option. Physicians promote shared decision-making by informing and educating patients, answering their questions, checking that they understand key issues, making recommendations, and helping them to deliberate. Medical jargon, needlessly complicated explanations, or the provision of too much information at once may overwhelm patients. Increasingly, decision aids can assist patients in playing a more active role in decision-making, improving the accuracy of their perception of risk and benefit, and helping them feel better informed and clearer about their values. Informed consent is more than obtaining signatures on consent forms and involves disclosure of honest and understandable information to promote understanding and choice. Competent, informed patients may refuse recommended interventions and choose among reasonable alternatives. In an emergency, treatment can be given without informed consent if patients cannot give their own consent and delaying treatment while surrogates are contacted would jeopardize patients' lives or health. People are presumed to want such emergency care unless they have previously indicated otherwise.

Respect for patients does not entitle patients to insist on any care or treatment that they want. Physicians are not obligated to provide interventions that have no physiologic rationale, that have already failed, or that are contrary to evidence-based practice recommendations or good clinical judgment. Public policies and laws also dictate certain decisions—e.g., allocation of scarce medical resources during a public health crisis such as the COVID-19 pandemic, use of cadaveric organs for transplantation, and requests for physician aid in dying.

CARING FOR PATIENTS WHO LACK DECISION-MAKING CAPACITY

Some patients are unable to make informed decisions because of unconsciousness, advanced dementia, delirium, or other medical conditions. Courts have the legal authority to determine that a patient is legally incompetent, but in practice, physicians usually determine when patients lack the capacity to make particular health care decisions and arrange for authorized surrogates to make decisions, without involving the courts. Patients with decision-making capacity can express a choice and appreciate their medical situation; the nature, risks, and benefits of proposed care; and the consequences of each alternative. Patient choices should be consistent with their values and not the result of delusions, hallucinations, or misinformation. Physicians should use available and validated assessment tools, resources such as psychiatry or ethics consultation, and clinical judgment to ascertain whether individuals have the capacity to make decisions for themselves. Patients should not be assumed to lack capacity if they disagree with recommendations or refuse treatment. Such decisions should be probed, however, to ensure the patient is not deciding based on misunderstandings and has the capacity to make an informed decision. When impairments are fluctuating or reversible, decisions should be postponed if possible until the patient recovers decision-making capacity.

When a patient lacks decision-making capacity, physicians seek an appropriate surrogate. Patients may designate a health care proxy through an advance directive or on a Physician Orders for Life-Sustaining Treatment form; such choices should be respected (see [Chap. 12](#)). For patients who lack decision-making capacity and have not previously designated a health care proxy, family members usually serve as surrogates. Statutes in most U.S. states delineate a prioritized list of relatives to make medical decisions. Patients' values, goals, and previously expressed preferences guide surrogate decisions. However, the patient's current best interests may sometimes justify overriding earlier preferences if an intervention is likely to provide significant benefit, previous statements do not fit the situation well, or the patient gave the surrogate leeway in decisions.

MAINTAINING CONFIDENTIALITY

Maintaining confidentiality is essential to respecting patients' autonomy and privacy; it encourages patients to seek treatment and to discuss problems candidly. However, confidentiality may be overridden to prevent serious harm to third parties or the patient. Exceptions to confidentiality are justified when the risk to others is serious and probable, no less restrictive measures can avert risk, and the adverse effects of overriding confidentiality are minimized and deemed acceptable by society. For example, laws require physicians to report cases of tuberculosis, sexually transmitted infection, elder or child abuse, and domestic violence.

Beneficence or Acting in Patients' Best Interests

The principle of *beneficence* requires physicians to act for the patient's benefit. Patients typically lack medical expertise, and illness may make them vulnerable. Patients rely on and trust physicians to treat them with compassion and provide sound recommendations and treatments aimed to

promote their well-being. Physicians encourage such trust and have a fiduciary duty to act in the best interests of patients, which should prevail over physicians' self-interest or the interests of third parties such as hospitals or insurers. A principle related to beneficence, "first do no harm," obliges physicians to prevent unnecessary harm by recommending interventions that maximize benefit and minimize harm and forbids physicians from providing known ineffective interventions or acting without due care. Although often cited, this precept alone provides limited guidance because many beneficial interventions also pose serious risks.

Physicians increasingly provide care within interdisciplinary teams and rely on consultation with or referral to specialists. Team members and consultants contribute different types of expertise to the provision of comprehensive, high-quality care for patients. Physicians should collaborate with and respect the contributions of the various interdisciplinary team members and should initiate and participate in regular communication and planning to avoid diffusion of responsibility and ensure accountability for quality patient care.

INFLUENCES ON PATIENTS' BEST INTERESTS

Conflicts arise when patients' refusal or request of interventions thwarts their own goals for care, causes serious harm, or conflicts with their best medical interests. For example, simply accepting a young asthmatic adult's refusal of mechanical ventilation for reversible respiratory failure, in the name of respecting autonomy, is morally constricted. Physicians should elicit patients' expectations and concerns, correct their misunderstandings, and try to persuade them to accept beneficial therapies. If disagreements persist after such efforts, physicians should call on institutional resources for assistance, but patients' informed choices and views of their own best interests should prevail.

Drug prices and out-of-pocket expenses for patients have been escalating in many parts of the world and may compromise care that is in the patients' best interests. Physicians should recognize that patients, especially those with high copayments or inadequate insurance, may not be able to afford prescribed tests and interventions. Physicians should strive to prescribe medications that are affordable and acceptable to the patient. Knowing what kind of insurance, if any, the patient has and whether certain medications are likely to be covered may help in determining appropriate prescriptions. Available alternatives should be considered and discussed. Physicians should follow up with patients who don't fill prescriptions, don't take their medications, or skip doses to explore whether cost and affordability are obstacles. It may be reasonable for physicians to advocate for coverage of nonformulary products for sound reasons, such as when the formulary drugs are less effective or not tolerated or are too costly for the patient to pay for out of pocket. These should be shared decisions with the patient to the extent possible.

Organizational policies and workplace conditions may sometimes conflict with patients' best interests. Physicians' focus and dedication to the well-being and interests of patients may be negatively influenced by perceived or actual staffing inadequacies, unfair wages, infrastructural deficiencies or lack of equipment, work-hour limitations, corporate culture, and threats to personal security in the workplace. Physicians should work with institutional leaders to ensure that policies and practices support their ability to provide quality care focused on patients' best interests.

Patients' interests are served by improvements in overall quality of care and the increasing use of evidence-based practice guidelines and performance benchmarking. However, practice guideline recommendations may not serve the interests of each individual patient, especially when another plan of care may provide substantially greater benefits. In prioritizing their duty to act in the patient's best interests, physicians should be familiar with relevant practice guidelines, be able to recognize situations that might justify exceptions, and advocate for reasonable exceptions.

Acting Justly

The principle of *justice* provides guidance to physicians about how to ethically treat patients and make decisions about allocating important resources, including their own time. *Justice* in a general sense means fairness: people should receive what they deserve. In addition, it is important to act consistently in cases that are similar in ethically relevant ways, in order to avoid arbitrary, biased, and unfair decisions. Justice forbids discrimination in health care based on race, religion, gender, sexual orientation, disability, age, or other personal characteristics ([Chap. 10](#)).

ALLOCATION OF RESOURCES

Justice also requires fair allocation of limited health care resources. Universal access to medically needed health care remains an unrealized moral aspiration in the United States and many countries around the world. Patients with no or inadequate health insurance often cannot afford health care and lack access to safety-net services. Even among insured patients, insurers may deny coverage for interventions recommended by their physician. In this situation, physicians should advocate for patients' affordable access to indicated care, try to help patients obtain needed care, and work with institutions and policies to promote wider access. Doctors might consider—or patients might request—the use of lies or deception to obtain such

benefits, for example, signing a disability form for a patient who does not meet disability criteria. Although motivated by a desire to help the patient, such deception breaches basic ethical guidelines and undermines physicians' credibility and trustworthiness.

Allocation of health care resources is unavoidable when resources are limited. Allocation policies should be fair, transparent, accountable, responsive to the concerns of those affected, and proportionate to the situation, including the supply relative to the need. In the 2019–2020 SARS-CoV-2/COVID-19 pandemic, some epicenters anticipated or faced shortages of staff, protective equipment, hospital and critical care beds, and ventilators, even after increasing supplies and modifying usual clinical procedures. Many jurisdictions developed guidelines for implementing crisis standards of care to allocate limited interventions and services. Under crisis standards of care, some aspects of conventional care are not possible and interventions may not be provided to all who might benefit or wish to receive them. Crisis standards of care aim to promote the good of the community by saving the most lives in the short term, using evidence-based criteria.

When demand for medications or other interventions exceeds the supply, allocation should be fair, strive to avoid discrimination, and mitigate health disparities. First-come, first-served allocation is not fair, because it disadvantages patients who experience barriers to accessing care. To avoid discrimination, allocation decisions should not consider personal social characteristics such as race, gender, or disability, nor consider insurance status or wealth. Allocation policies also should aspire to reduce health care disparities. U.S. African-American, Latino-American, and Native-American patients suffered a disproportionate number of COVID-19 cases and deaths, likely due in part to being employed in jobs that cannot be done remotely or with physical distancing, crowded housing, lack of health benefits, and poor access to health care.

Fair and well-considered guidelines help mitigate any emotional and moral distress that clinicians may experience making difficult allocation decisions. Authorizing triage officers or committees to make allocation decisions according to policies determined with public input allows treating physicians and nurses to dedicate their efforts to their patients. Ad hoc resource allocation by physicians at the bedside may be inconsistent, unfair, and ineffective. At the bedside, physicians should act as patient advocates within constraints set by society, reasonable insurance policies, and evidence-based practice. Many allocation decisions are made at the level of public policy, with physician and public input. For example, the United Network for Organ Sharing (www.unos.org) provides criteria for allocating scarce organs.

VIRTUE ETHICS

Virtue ethics focuses on physicians' character and qualities, with the expectation that doctors will cultivate virtues such as compassion, trustworthiness, intellectual honesty, humility, and integrity. Proponents argue that, if such characteristics become ingrained, they help guide physicians in unforeseen situations. Moreover, following ethical precepts or principles without any of these virtues could lead to uncaring doctor–patient relationships.

PROFESSIONAL OATHS AND CODES

Professional oaths and codes are useful guides for physicians. Most physicians take oaths during their medical training, and many are members of professional societies that have professional codes. Physicians pledge to the public and to their patients that they will be guided by the principles and values in these oaths or codes and commit to the spirit of the ethical ideals and precepts represented in oaths and professional codes of ethics.

PERSONAL VALUES

Personal values, cultural traditions, and religious beliefs are important sources of personal morality that help physicians address ethical issues and cope with any moral distress they may experience in practice. While essential, personal morality alone is a limited ethical guide in clinical practice. Physicians have role-specific ethical obligations that go beyond their obligations as good people, including the duties to obtain informed consent and maintain confidentiality discussed earlier. Furthermore, in a culturally and religiously diverse world, physicians should expect that some patients and colleagues will have personal moral beliefs that differ from their own.

ETHICALLY COMPLEX PROFESSIONAL ISSUES FOR PHYSICIANS

CLAIMS OF CONSCIENCE

Some physicians, based on their personal values, have conscientious objections to providing, or referring patients for, certain treatments such as contraception or physician aid in dying. Although physicians should not be asked to violate deeply held moral beliefs or religious convictions, patients

need medically appropriate, timely care and should always be treated with respect. Institutions such as clinics and hospitals have a collective ethical duty to provide care that patients need while making reasonable attempts to accommodate health care workers' conscientious objections—for example, when possible by arranging for another professional to provide the service in question. Patients seeking a relationship with a doctor or health care institution should be notified in advance of any conscientious objections to the provision of specific interventions. Since insurance often constrains patients' selection of physicians or health care facilities, switching providers can be burdensome. There are also important limits on claims of conscience. Health care workers may not insist that patients receive unwanted medical interventions. They also may not refuse to treat or discriminate against patients because of their race, ethnicity, disability, genetic information, or diagnosis. Such discrimination is illegal and violates physicians' duties to respect patients. Refusal to treat patients for other reasons such as sexual orientation, gender identity, or other personal characteristics is legally more controversial, yet ethically inappropriate because it falls short of helping patients in need and respecting them as persons.

PHYSICIAN AS GATEKEEPER

In some cases, patients may ask their physicians to facilitate access to services that the physician has ethical qualms about providing. For example, a patient might request a prescription for a cognitively enhancing medication to temporarily augment his cognitive abilities in order to take an exam or apply for employment. Patients may request more pain medication than the physician believes is warranted for the given situation or marijuana to facilitate sleep. Patients may ask their physician to sign a waiver to avoid vaccines for reasons that are not included in state exceptions (see [Chap. 3](#)). A physician may feel uncomfortable prescribing attention-deficit/hyperactivity disorder medications to a young child because she is not convinced that the possible benefit justifies the risks to the child despite the parent's request. In these circumstances, the physician should work with the patient or parent to understand the reasons for their requests, some of which might be legitimate. In addition to considering possible risks and benefits to the patient, the physician should consider how meeting the request might affect other patients, societal values, and public trust in the medical profession. If the physician determines that fulfilling the request requires deception, is unfair, jeopardizes her professional responsibilities, or is inconsistent with the patient's best medical interests, the physician should decline and explain the reasons to the patient.

MORAL DISTRESS

Health care providers, including residents, medical students, and experienced physicians, may experience moral distress when they feel that ethically appropriate action is hindered by institutional policies or culture, decision-making hierarchies, limited resources, or other reasons. Moral distress can lead to anger, anxiety, depression, frustration, fatigue, work dissatisfaction, and burnout. A physician's health and well-being can affect how he or she cares for patients. Discussing complex or unfamiliar clinical situations with colleagues and seeking assistance with difficult decisions can help alleviate moral distress, as can a healthy work environment characterized by open communication, mutual respect, and emphasis on the common goal of good patient care. In addition, physicians should take good care of their own well-being and be aware of the personal and system factors associated with stress, burnout, and depression. Health care organizations should provide a supportive work environment, counseling, and other support services when needed.

OCCUPATIONAL RISKS AND BURDENS

Physicians accept some physical risk in fulfilling their professional responsibilities, including exposure to infectious agents or toxic substances, violence in the workplace, and musculoskeletal injury. Nonetheless, most physicians, nurses, and other hospital staff willingly care for patients, despite personal risk and fear, grueling hours, and sometimes inadequate personal protective equipment or information. During the COVID-19 pandemic, many communities honored clinicians' dedication to professional ideals, and some medical students who were relieved from in-person patient care responsibilities volunteered to support front-line workers in other ways. The burdens of navigating professional and personal responsibilities fall more heavily on women health care providers. Health care institutions are responsible for reducing occupational risk and burden by providing proper information, training and supervision, protective equipment, infrastructure and workflow modifications, and emotional and psychological support to physicians. Clinical leaders need to acknowledge fears about personal safety and take steps to mitigate the impact of work on family responsibilities, moral distress, and burnout.

USE OF SOCIAL MEDIA AND PATIENT PORTALS

Increasingly, physicians use social and electronic media to share information and advice with patients and other providers. Social networking may be especially useful in reaching young or otherwise hard-to-access patients. Patients increasingly access their physicians' notes through patient portals,

which aim to transparently share information, promote patient engagement, and increase adherence. Physicians should be professional and respectful and consider patient confidentiality, professional boundaries, and therapeutic relationships when posting to social media or writing notes for the portal. Overall, appropriate use of these platforms can enhance communication and transparency while avoiding misunderstandings or harmful consequences for patients, physicians, or their colleagues. Unprofessional or careless posts that express frustration or anger over work incidents, disparage patients or colleagues, use offensive or discriminatory language, or reveal inappropriate personal information about the physician can have negative consequences. Physicians should separate professional from personal websites and accounts and follow institutional and professional society guidelines when communicating with patients.

CONFLICTS OF INTEREST

Acting in patients' best interests may sometimes conflict with a physician's self-interest or the interests of third parties such as insurers or hospitals. From an ethical viewpoint, patients' interests are paramount. Transparency, appropriate disclosure, and management of conflicts of interest are essential to maintain the trust of colleagues and the public. Disclosure requirements vary for different purposes, and software has been developed to assist physicians in complying with specific requirements. Importantly, not all conflicts are financial. Physicians sometimes face conflicts of commitment between their patient's interests and their own personal interests, professional goals, responsibilities, and aspirations. As mentioned earlier, physicians should prioritize patients' interests while recognizing possible conflicts and using disclosure, discussion with the chief of service, and management of the conflict or recusal when appropriate.

In addition to individual physicians, medical institutions may have conflicts of interest arising from patent rights, industry-funded research programs, and donations from individuals and companies. Institutions need to be transparent about the presence and amount of such relationships and make clear the steps taken to prevent such relationships from having an impact on clinical or financial decisions. If there is good evidence that a donor acted in ways that breached ethical or legal standards, the institution should take steps not to benefit from the donation or honor the donor.

FINANCIAL INCENTIVES

Physicians have financial incentives to improve the quality or efficiency of care that might lead some to avoid patients who are older, are chronically ill, or have more complicated problems, or to focus on benchmarked outcomes even when not in the best interests of individual patients. In contrast, fee-for-service payments might encourage physicians to order more interventions than necessary or to refer patients to laboratory, imaging, or surgical facilities in which they have a financial stake. Regardless of financial incentives, physicians should recommend available care that is in the patient's best interests—no more and no less.

RELATIONSHIPS WITH PHARMACEUTICAL COMPANIES

Financial relationships between physicians and industry are increasingly scrutinized. Many academic medical centers have banned drug-company gifts, including branded pens and notepads and meals to physicians, to reduce inappropriate risk of undue influence or subconscious feelings of reciprocity and to decrease possible influences on public trust or the costs of health care.

The federal Open Payments website provides public information on the payments and amounts that drug and device companies give to individual physicians by name. The challenge is to distinguish payments for scientific consulting and research contracts—which should be encouraged as consistent with professional and academic missions—from those for promotional speaking and consulting whose goal is to increase sales of company products.

LEARNING CLINICAL SKILLS

Medical students', residents', and physicians' interests in learning, which fosters the long-term goal of benefiting future patients, may sometimes conflict with the short-term goal of providing optimal care to current patients. When trainees are learning procedures on patients, they lack the proficiency of experienced physicians, and patients may experience inconvenience, discomfort, longer procedures, or increased risk. Increasingly, institutions are developing clinical skills laboratories for simulation-based medical education and requiring students to demonstrate proficiency before carrying out procedures such as venipuncture and intravenous lines in patients. Furthermore, teaching hospitals are establishing proceduralist services in which procedure-specialist faculty members directly supervise interns for procedures such as lumbar puncture and thoracentesis and certify their proficiency. Medical students may need to defer learning such invasive procedures until internship. Seeking patients' consent for trainee

participation in their care is always important and is particularly important for intimate examinations, such as pelvic, rectal, breast, and testicular examinations, and for invasive procedures. Patients should be told who is providing care and how trainees are supervised. Failing to introduce students or not telling patients that trainees will be performing procedures undermines trust, may lead to more elaborate deception, and makes it difficult for patients to make informed choices about their care. Most patients, when informed, allow trainees to play an active role in their care.

RESPONSE TO MEDICAL ERRORS

Errors are inevitable in clinical medicine, and some errors cause harm to patients. Most errors are caused by lapses of attention or flaws in the system of delivering health care; only a small number result from blameworthy individual behavior. Many health care institutions have adopted a just culture system, which encourages open and honest reporting of errors as essential to quality learning and shifts the focus from individual blame to system design for improvement in quality and safety (**Chap. 8**). This approach is more likely than a punitive approach to improve patient safety. However, professional discipline is appropriate for cases of gross incompetence, reckless behavior, physician impairment, and boundary violations. Physicians and students may fear that disclosing errors will damage their careers. Physicians and health care institutions show respect for patients by disclosing and explaining errors, offering an apology, offering appropriate compensation for harm done, and using errors as opportunities to improve the quality of care.

PHYSICIAN IMPAIRMENT

Physicians may hesitate to intervene when colleagues impaired by **alcohol**, drugs, or psychiatric or medical illness place patients at risk. However, society relies on physicians to regulate themselves. Colleagues of an impaired physician should take steps to protect patients and help their impaired colleague, starting with reporting their concerns to their clinical supervisor or director.

ETHICAL ISSUES IN CLINICAL RESEARCH

Clinical research is essential to translate scientific discoveries into beneficial interventions for patients. However, clinical research raises ethical concerns because participants face inconvenience and risks in research designed to advance scientific knowledge and not specifically to benefit them. Ethical guidelines require researchers to rigorously design and conduct research, minimize risk to participants, and obtain informed and voluntary consent from participants and approval from an institutional review board (IRB). IRBs determine that risks to participants are acceptable and have been minimized and recommend appropriate additional protections when research includes vulnerable participants.

Physicians may be clinical research investigators themselves or may be in a position to refer or recommend clinical trial participation to their patients. Physician-investigators are likely to feel some inherent tension between conducting research and providing health care. Awareness of this tension, familiarity with research ethics, collaboration with research and clinical team members, and utilizing research ethics consultation can help to mitigate tensions. Before starting clinical research, investigators should complete training in the ethics of clinical research, which is widely available.

Physicians also should be critical consumers of clinical research results and keep up with research advances that change standards of practice. Precision medicine initiatives aim to individualize clinical care by combining clinical information from electronic health records, genomic sequencing, and data from personal mobile devices. Furthermore, physicians and health care institutions are analyzing data routinely collected and available in electronic health records, leftover clinical specimens, and administrative data. Such studies encompass traditional discovery research as well as quality improvement, comparative effectiveness research, and learning health care systems. Efforts to improve the quality of care in real-world clinical settings are important but also raise new issues about informed consent, privacy, and risk.

EMERGING TECHNOLOGIES

Scientific advances in genome sequencing, gene editing (e.g., with CRISPR-Cas9), machine learning, artificial intelligence, computer-brain interfaces, and other technologies offer great promise for research and clinical care with the ultimate goal of improving the prediction, prevention, and treatment of disease. Groundbreaking innovations that have strong scientific plausibility need to be evaluated in rigorous clinical studies for efficacy and safety.

Physicians should keep up to date on the status of novel and often complex technologies as research evolves, data emerge, and technologies are incorporated into clinical practice. They can help their patients understand research findings and the evidence for clinical use, correct any misunderstandings, facilitate shared decision-making, and advocate for fair access to such therapies. Further, physicians should engage in

professional and public discussion related to allocation of resources and fair access to expensive new therapies and emerging technologies and their impact on overall health care affordability.

Certain cell-based therapies, such as peripheral blood stem cell transplantation (**Chap. 114**) and chimeric antigen receptor (CAR)-T cell therapy (**Chap. 69**), are approved for use in several serious hematologic cancers, and gene therapies have been approved as safe and effective for clinical use in certain serious inherited diseases and cancers. Patients may request these and other complex, highly technical, and expensive therapies for unproven indications. Yet, claims of cures through unproven stem cell or gene-based “therapies” pose significant health and financial risks to patients without evidence of benefit. Physicians should help patients distinguish approved therapies from unproven claims and refer interested patients to well-designed clinical trials.

Medical applications of CRISPR-Cas9 are promising, and their safety and efficacy for particular clinical conditions are being carefully evaluated in clinical trials. Applications of CRISPR genome editing in somatic cells to modify or correct problematic genes could lay the foundation for treating a variety of serious diseases, including blood disorders, HIV, cancer, and hereditary blindness. Germline gene editing in blastocysts or embryos raises many ethical questions and is currently not permitted in the United States in clinical trials or clinical practice.

In artificial intelligence (AI), computers carry out tasks typically done by humans. Machine learning (ML) is a type of AI that automatically learns and improves its performance without explicit programming. Clinical algorithms using AI and ML can make diagnoses from radiology images, retinal scans, or skin photographs and identify patients at increased risk for surgical complications, critical care, or hospital readmission. However, such algorithms can also pose risks. Bias may occur if an algorithm was derived or validated from a data set in which groups who suffer from health disparities or poor health outcomes are underrepresented or if the algorithm predicts outcomes that are not clinically meaningful. To address these ethical concerns, researchers should assess AI algorithms in well-designed randomized clinical trials with clinical endpoints. Institutions should integrate validated and unbiased algorithms into clinical workflow without unduly burdening physicians and nurses and should check effectiveness and safety in their particular settings and patient populations.

Physicians should stay informed of emerging evidence about such technologies and the ethical challenges that accompany their use and always keep their patients’ best interests and preferences at the forefront.

GLOBAL CONSIDERATIONS

INTERNATIONAL RESEARCH

Clinical research is often conducted across multiple sites and across national borders. Societal, legal, and cultural norms and perspectives about research may vary, and there are many ethical challenges. Physician-investigators involved in international research should be familiar with international guidelines, such as the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) guidelines, and the International Council on Harmonisation Good Clinical Practice guidelines, as well as national and local laws where research is taking place. Partnering with local researchers and communities is essential not only to demonstrate respect but also to facilitate successful clinical research.

INTERNATIONAL CLINICAL EXPERIENCES

Many physicians and trainees gain valuable experience providing patient care in international settings through international training opportunities or volunteering for humanitarian or other international clinical work. Such arrangements, however, raise ethical challenges—for example, as a result of differences in beliefs about health and illness, expectations regarding health care and physicians’ roles, standards of clinical practice, resource limitations, and norms for disclosure of serious diagnoses. Additional dilemmas arise if visiting physicians and trainees take on responsibilities beyond their expertise or if donated drugs and equipment are not appropriate to local needs. Visiting physicians and trainees should prepare well for these experiences, receive training and mentoring, learn about cultural and clinical practices in the host community, respect local customs and values, collaborate closely with local professionals and staff, and be explicit and humble about their own skills, knowledge, and limits. Leaders of global health field experiences should ensure that participating physicians receive training on ethical and cultural issues, as well as mentoring, backup, and debriefing upon return home.

CONCLUSION

Ethical issues are common in clinical medicine and occur in circumstances that may be foreseeable, novel, or unexpected. Physicians address these ethical issues by being prepared, informed, and thoughtful and using appropriate available resources.

FURTHER READING

Beauchamp T, Childress J: *Principles of Biomedical Ethics*, 8th ed. New York, Oxford University Press, 2019.

Dejong C et al: An ethical framework for allocating scarce medications for COVID-19 in the US. *JAMA* 323:2367, 2020. [[PubMed: 32412580](#)]

Matheny M et al (eds): *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril*. NAM Special Publication. Washington, DC, National Academy of Medicine, 2019.

Ulrich C, Grady C: *Moral Distress in the Health Professions*. Cham, Switzerland, Springer-Nature International, 2018.

Wasserman J et al: Responding to unprofessional behavior by trainees: a “just culture” framework. *N Engl J Med* 382:773, 2020. [[PubMed: 32074428](#)]

Wicclair MR: Conscientious objection, moral integrity, and professional obligations. *Perspect Biol Med* 62:543, 2019. [[PubMed: 31495797](#)]