

American College of Physicians Ethics Manual

Seventh Edition

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Medicine, law, and social values are not static. Reexamining the ethical tenets of medicine and their application in new circumstances is a necessary exercise. The seventh edition of the American College of Physicians (ACP) Ethics Manual covers emerging issues in medical ethics and revisits older ones that are still very pertinent. It reflects on many of the ethical tensions in medicine and attempts to shed light on how existing principles extend to emerging concerns. In addition, by reiterating ethical principles

that have provided guidance in resolving past ethical problems, the Manual may help physicians avert future problems. The Manual is not a substitute for the experience and integrity of individual physicians, but it may serve as a reminder of the shared duties of the medical profession.

Ann Intern Med. 2019;170:S1-S32. doi:10.7326/M18-2160

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The secret of the care of the patient is in caring for the patient.

—Francis Weld Peabody (1)

Some aspects of medicine, such as the patient-physician relationship, are fundamental and timeless. Medicine, however, does not stand still—it evolves. Physicians must be prepared to deal with relevant changes and reaffirm what is fundamental. This seventh edition of the Ethics Manual examines emerging issues in medical ethics and professionalism and revisits older issues that are still very pertinent. Major changes to the Manual since the 2012 (sixth) edition (2) include new or expanded sections on electronic communications; telemedicine ethics; electronic health record ethics; precision medicine and genetics; social media and online professionalism; the changing practice environment; population health; physician volunteerism; research and protection of human subjects; and a revised case method for ethics decision making (Appendix).

Changes to the Manual from the sixth edition are noted in Box 1.

The Manual is intended to facilitate the process of making ethical decisions in clinical practice, teaching, and medical research and to describe and explain underlying principles of ethics, as well as the physician's role in society and with colleagues. Because ethics and professionalism must be understood within a historical and cultural context, the second edition of the Manual included a brief overview of the cultural, philosophical, and religious underpinnings of medical ethics in Western cultures. In this edition, we refer the reader to that overview (3, 4) and to other sources (5, 6) that more fully explore this rich heritage.

The Manual raises issues and presents general guidelines. In applying these guidelines, physicians

should consider the circumstances of the individual patient and use their best judgment. Physicians have ethical and legal obligations, and the two may not be concordant. Physician participation in torture is legal in some countries but is never ethical. Physicians must keep in mind the distinctions and potential conflicts between legal and ethical obligations and seek counsel when concerned about the potential legal consequences of decisions. We refer to the law in this Manual for illustrative purposes only; this should not be taken as a statement of the law or the legal consequences of actions, which can vary by state and country. Physicians must develop and maintain an adequate knowledge of key components of the laws and regulations that affect their patients and practices.

Medical and professional ethics often establish positive duties (that is, what one should do) to a greater extent than the law. Current understanding of medical ethics is based on the principles from which positive duties emerge (Table 1). These principles include beneficence (the duty to promote good and act in the best interest of the patient) and nonmaleficence (the duty to do no harm to the patient). Also included is respect for patient autonomy—the duty to protect and foster a patient's free, uncoerced choices (7). From the principle of respect for autonomy are derived the rules for truth-telling. The relative weight granted to these principles and the conflicts among them often account

See also:

Editorial comment 133

Web-Only
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Box 1. Changes to the Manual since the 2012 (sixth) edition.

New or expanded sections on:
 Electronic communications
 Telemedicine ethics
 Electronic health records
 Precision medicine and genetics
 Caring for oneself, persons with whom the physician has a preexisting close nonprofessional relationship or a reporting relationship, and "very important persons"
 Social media and online professionalism
 The changing practice environment
 Gifts from patients
 Population health
 Physician volunteerism
 Research and protection of human subjects
 Innovative medical therapies and research
 Internet and social media research

A revised case method for clinical ethics decision making (Appendix)

for the ethical dilemmas we face. Physicians who will be challenged to resolve those dilemmas must have such virtues as compassion, courage, and patience.

In addition, considerations of justice must inform the physician's role as citizen and clinical decisions about resource allocation. The principle of distributive justice requires that we seek to equitably distribute the life-enhancing opportunities afforded by health care. How to accomplish this distribution is the focus of intense debate. More than ever, concerns about justice and about the health of society challenge the role of physician as patient advocate.

The environment for the delivery of health care continues to change. Sites of care are shifting, with more care provided in ambulatory settings while the intensity of inpatient care increases. The U.S. health care system does not serve all of its people well, and major reform has been needed. Health care financing is a serious concern, and society's values will be tested in decisions about resource allocation.

Ethical issues attract widespread public attention and debate. Through legislation, administrative action, or judicial decision, government is increasingly involved in issues of medical ethics and clinical practice. The convergence of various forces—scientific advances, patient and public education, the Internet, the civil rights and consumer movements, the effects of law and economics on medicine, and the heterogeneity of our society—demands that physicians clearly articulate the ethical principles that guide their behavior in clinical care, research, and teaching, or as citizens or collectively as members of the profession. It is crucial that a responsible physician perspective be heard as societal decisions are made.

From genetic testing before conception to dilemmas at the end of life, patients and their families (8), with their physicians, are called upon to make difficult decisions. The 1970s saw the development of bioethics as a field. Important issues then (and now) include informed consent, confidentiality and privacy, access to

health care, conflicts of interest, genetics and precision medicine, and care of the dying. Technological, systems, and other changes continue to affect the patient-physician relationship and issues from changing communication modalities and payment models for care to the physician as entrepreneur or as employee challenge us as we apply and reaffirm principles of medical ethics.

This Manual was written for our colleagues in medicine. The College believes that the Manual provides the best approach to the challenges addressed in it. We hope it stimulates reasoned arguments and debate and serves as a reference for all who seek the College's position on ethical issues. Debates about medical ethics may also stimulate critical evaluation and discussion of law and public policy on the difficult ethical issues facing patients, physicians, and society.

METHODS

The American College of Physicians (ACP) Ethics, Professionalism and Human Rights Committee (EPHRC) oversees development of the editions of the ACP Ethics Manual. The Manual was first published in 1984 and is reviewed and updated every 5 to 7 years. Committee members abide by ACP's conflict-of-interest policy and procedures (www.acponline.org/about-acp/who-we-are/acp-conflict-of-interest-policy-and-procedures), and appointment to and procedures of the EPHRC are governed by the ACP's bylaws (www.acponline.org/about-acp/who-we-are/acp-bylaws).

After an environmental assessment to determine the scope of issues and literature reviews, over the course of 8 meetings, the EPHRC evaluated each section of the Manual to make any additions or changes. The draft was reviewed by members of the ACP Board of Governors, Board of Regents, Council of Resident/Fellow Members, Council of Student Members, and other committees and experts, and all input was considered in the revisions to the Manual. The ACP Board of Regents reviewed and approved the Manual on 5 June 2018.

The Ethics Manual is official ACP policy. ACP members pledge "to uphold the ethics of medicine as exemplified by the standards and traditions of this College," and we hope the Manual is a resource to all physicians and to others, as well.

Table 1. Principles That Guide the ACP Ethics Manual Recommendations

Principle	Description
Beneficence	The duty to promote good and act in the best interest of the patient
Nonmaleficence	The duty to do no harm to the patient
Respect for patient autonomy	The duty to protect and foster a patient's free, uncoerced choices
Justice	The equitable distribution of the life-enhancing opportunities afforded by health care

Box 2. Definition of *profession* as used in the Manual.

A profession is characterized by a specialized body of knowledge that its members must teach and expand; by a code of ethics and a duty of service that in medicine, puts patient care above self-interest; and by the privilege of self-regulation granted by society.

PROFESSIONALISM

“The practice of medicine is an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head,” said William Osler (9). Medicine is not, as Francis Peabody said, “a trade to be learned, but a profession to be entered” (1). A profession is characterized by a specialized body of knowledge that its members must teach and expand; by a code of ethics and a duty of service that, in medicine, puts patient care above self-interest; and by the privilege of self-regulation granted by society (10). Physicians must individually and collectively fulfill the duties of the profession. The ethical foundations of the profession must remain in sharp focus despite outside influences on medicine, individuals, and the patient-physician relationship (11, 12).

The definition of *profession* is noted in **Box 2**.

THE PHYSICIAN AND THE PATIENT

The patient-physician relationship entails special obligations for the physician to serve the patient's interest because of the specialized knowledge that physicians possess, the confidential nature of the relationship, the vulnerability brought on by illness, and the imbalance of expertise and power between patient and physician. Physicians publicly profess that they will use their skills for the benefit of patients, not for other reasons, including their own benefit (13). Physicians must uphold this declaration, as should their professional associations as communities of physicians that put patient welfare first (13).

The physician's primary commitment must always be to the patient's welfare and best interests, whether in preventing or treating illness or helping patients to cope with illness, disability, and death. The physician must respect the dignity of all persons and respect their uniqueness. The interests of the patient should always be promoted regardless of financial arrangements; the health care setting; or patient characteristics, such as decision-making capacity, behavior, or social status. Although the physician should be fairly compensated for medical services, a sense of duty to the patient should take precedence over concern about compensation.

Initiating and Discontinuing the Patient-Physician Relationship

At the beginning of and throughout the patient-physician relationship, the physician must work toward an understanding of the patient's health problems, concerns, values, goals, and expectations. After patient and physician agree on the problem and the goals of

care, the physician presents one or more courses of action, with a specific recommendation for the patient. The patient may authorize the physician to initiate a course of action; the physician can then accept that responsibility. The relationship has mutual obligations. The physician must be professionally competent, act responsibly, seek consultation when necessary, and treat the patient with compassion and respect, and the patient should participate responsibly in the care including through informed decision making, giving consent to or declining treatment as the case might be.

Effective communication is critical to a strong patient-physician relationship. The physician has a duty to promote patient understanding and should be aware of barriers, including health literacy issues for the patient. Communication through e-mail or other electronic means can supplement in-person encounters; however, it must be done under appropriate guidelines (14). E-mail or other electronic communications should only be used by physicians in an established patient-physician relationship and with patient consent (15). Documentation about patient care communications should be included in the patient's medical record.

Guidance on patient-physician e-communication is noted in **Box 3**.

Aspects of a patient-physician relationship, such as the physician's responsibilities to the patient, remain operative even in the absence of in-person contact between the physician and patient (16). “Issuance of a prescription or other forms of treatment, based only on an online questionnaire or phone-based consultation does not constitute an acceptable standard of care” (16). Exceptions to this may include on-call situations in which the patient has an established relationship with another clinician in the practice and certain urgent public health situations, such as the diagnosis and treatment of communicable infectious diseases. An example is the Centers for Disease Control and Prevention-endorsed practice of expedited partner therapy for certain sexually transmitted infections.

Care and respect should guide the performance of the physical examination. The location and degree of privacy should be appropriate for the examination being performed, with chaperone services as an option.

Box 3. Patient-physician e-communication.

Effective communication is critical to a strong patient-physician relationship.

Communication through e-mail or other electronic means can supplement in-person encounters but must be done under appropriate guidelines.

E-communications should only be used by physicians in an established patient-physician relationship and with patient consent.

Documentation about all patient care communications should be in the patient's medical record.

Aspects of a patient-physician relationship, such as the physician's responsibilities to the patient, remain operative.

Box 4. Telemedicine and ethics.

There must be a valid patient–physician relationship for a professionally responsible telemedicine service to take place.

A telemedicine encounter itself can establish a patient–physician relationship through real-time, technically appropriate audiovisual technology.

In the absence of direct previous contact or an existing relationship before a telemedicine encounter, the physician must take appropriate steps to establish a relationship based on the standard of care required for an in-person visit, or consult with another physician who does have a relationship with the patient.

The benefits of increased access to care through telemedicine must be balanced with risks from the loss of the in-person encounter—for example, misdiagnosis potential; overprescribing; absent in-person interactions, including the therapeutic value of touch, and body language; and continuity of care.

An appropriate setting and sufficient time should be allocated to encourage exploration of aspects of the patient's life pertinent to health, including habits, relationships, sexuality, vocation, culture, religion, and spirituality.

In the context of telemedicine, there must be a valid patient–physician relationship for a professionally responsible telemedicine service to take place (17). A telemedicine encounter itself can establish a patient–physician relationship through real-time, technically appropriate audiovisual technology. When there has been no direct previous contact or existing relationship with a patient before a telemedicine encounter, the physician must take appropriate steps to establish a relationship based on the standard of care required for an in-person visit, or consult with another physician who does have a relationship with the patient. The benefits of opportunities for increased access to care through telemedicine “must be balanced according to the nature of the particular encounter and the risks from the loss of the in-person encounter (such as the potential for misdiagnosis; inappropriate testing or prescribing; and the loss of personal interactions that include the therapeutic value of touch, communications with body language, and continuity of care)” (17).

Guidance on telemedicine is noted in **Box 4**.

By history, tradition, and professional oath, physicians have a moral obligation to provide care for ill persons. Although this obligation is collective, each individual physician is obliged to do his or her fair share to ensure that all ill persons receive appropriate treatment (18). A physician may not discriminate against a class or category of patients.

An individual patient–physician relationship is formed on the basis of mutual agreement. In the absence of a preexisting relationship, the physician is not ethically obliged to provide care to an individual person unless no other physician is available, as is the case in some isolated communities, or when emergency treatment is required. Under these circumstances, the physician is ethically bound to provide care and, if nec-

essary, to arrange for proper follow-up. Physicians may also be bound by contract to provide care to beneficiaries of health plans in which they participate.

Physicians and patients may have different concepts of or cultural beliefs about the meaning and resolution of medical problems. The care of the patient and satisfaction of both parties are best served if physician and patient discuss their expectations and concerns. Although the physician must address the patient's concerns, he or she is not required to violate fundamental personal values, standards of medical care or ethical practice, or the law. When the patient's beliefs—religious, cultural, or otherwise—run counter to medical recommendations, the physician is obliged to try to understand clearly the beliefs and viewpoints of the patient. If the physician cannot carry out the patient's wishes after seriously attempting to resolve differences, the physician should discuss with the patient his or her option to seek care from another physician.

The physician's responsibility is to serve the best interests of the patient. Under rare circumstances, the physician may elect to discontinue the professional relationship, provided that adequate care is available elsewhere and the patient's health is not jeopardized in the process (19, 20). The physician should notify the patient in writing, offer to transfer the medical records to another physician with patient approval, and comply with applicable laws. Continuity of care must be assured. Physician-initiated termination is a serious event, especially if the patient is acutely ill, and should be undertaken only after genuine attempts to understand and resolve differences. Abandonment is unethical and a cause of action under the law. A patient is free to change physicians at any time and is entitled to the information contained in the medical records.

Third-Party Evaluations

Performing a limited assessment of an individual on behalf of a third party, for example, as an industry-employed physician or an independent medical examiner, raises distinct ethical issues regarding the patient–physician relationship. The physician should disclose to the patient that an examination is being undertaken on behalf of a third party that therefore raises inherent conflicts of interest; ensure that the patient is aware that traditional aspects of the patient–physician relationship, including confidentiality, might not apply; obtain the examinee's consent to the examination and to the disclosure of the results to the third party; exercise appropriate independent medical judgment, free from the influence of the third party; and inform the examinee of the examination results and encourage her or him to see another physician if those results suggest the need for follow-up care (21, 22).

Confidentiality

Confidentiality is a fundamental tenet of medical care. It is increasingly difficult to maintain in this era of electronic health records and electronic data processing, patient portals, e-mail, texting, faxing of patient information, third-party payment for medical services, and sharing of patient care among numerous health

professionals and institutions. Physicians must follow appropriate security protocols for storage and transfer of patient information to maintain confidentiality, adhering to best practices for electronic communication and use of decision-making tools.

Privacy is freedom from unauthorized intrusion. Confidentiality is a matter of respecting the privacy of patients, encouraging them to seek medical care and discuss their problems candidly, and preventing discrimination on the basis of their medical conditions. The physician should not release a patient's personal medical information (often termed a "privileged communication") without that patient's consent. The commitment to confidentiality is based on the duty of non-maleficence and on respect for persons and autonomy.

However, confidentiality, like other ethical duties, is not absolute. It may have to be overridden to protect individuals or the public or to disclose or report information when the law requires it. The physician should make every effort to discuss the issues with the patient. If breaching confidentiality is necessary, it should be done in a way that minimizes harm to the patient and heeds applicable federal and state law.

Physicians should be aware of the increased risk for invasion of patient privacy and should help ensure confidentiality. They should be aware of state and federal law, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) (23, 24). Within their own institutions, physicians should advocate policies and procedures to secure the confidentiality of patient records. To uphold professionalism and protect patient privacy, clinicians should limit discussion of patients and patient care issues to professional encounters. Discussion of patients by professional staff in public places, including elevators or cafeterias, violates confidentiality and is unethical. Outside of an educational setting, discussion of patients with or near persons who are not involved in the care of those patients can impair the public's trust and confidence in the medical profession. Physicians of patients who are well known to the public should remember that they are not free to discuss or disclose information about any person's health without his or her explicit consent.

In the care of the adolescent patient, family support is important. However, this support must be balanced with confidentiality and respect for the adolescent's autonomy in health care decisions and in relationships with clinicians (25). Physicians should be knowledgeable about challenges to confidentiality (26), state laws governing the right of adolescent patients to confidentiality, and the adolescent's legal right to consent to treatment.

Occasionally, a physician receives information from a patient's friends or relatives and is asked to withhold the source of that information from the patient (27). The physician is not obliged to keep such secrets from the patient. The informant should be urged to address the patient directly and to encourage the patient to discuss the information with the physician. The physician

should use sensitivity and judgment in deciding whether to use the information and whether to reveal its source to the patient. The physician should always act in the best interests of the patient.

The Medical Record

Physician entries in the medical record, paper and electronic, should contain accurate and complete information about all communications, including those done in-person and by telephone, letter, or electronic means. Ethically and legally, patients have the right to know what is in their medical records. Legally, the medical record is the property of the physician or institution, although the information in the record is the property of the patient. Most states have laws that guarantee the patient personal access to the medical record, as do federal privacy rules. The physician must release information to the patient or to a third party at the request of the patient. Information may not be withheld, including because of nonpayment of medical bills. To protect confidentiality, protected health information should be released only with the written permission of the patient or the patient's legally authorized representative, or as required by law.

Electronic health records (EHRs) and computer use facilitate patient care and should align with physician ethical duties in supporting the patient-physician relationship (28). The EHR should assist and enhance clinical reasoning and the development of cognitive and diagnostic skills; for example, copy-and-paste (29) and other features should be used carefully and only if they help reflect the physician's thought processes about the current patient encounter and produce an accurate and complete medical record that meets ethical standards. Electronic health record information retrieval, exchange, and remote access can improve care, but also create risks, including unauthorized disclosure and use of protected health information (28).

If a physician leaves a group practice or dies, patients must be notified and records forwarded according to patient instructions. Physicians should be aware of applicable state laws and regulations with regard to retention of medical records.

Disclosure

To make health care decisions and work in partnership with the physician, the patient must be well informed. Effective patient-physician communication can dispel uncertainty and fear and enhance healing and patient satisfaction. Information should be disclosed to patients and, when appropriate, family caregivers or surrogates, whenever it is considered material to the understanding of the patient's situation, possible treatments or nontreatment, and probable outcomes. This information often includes the burdens of treatment, the experience of the proposed clinician, the nature of the illness, and potential treatments and costs.

How and when to disclose information, and to whom, are important concerns that must be addressed with respect for patient wishes. In general, individuals have the right to full and detailed disclosure. Some patients, however, may make it known that they prefer

limited information or disclosure to family members or others they choose (30).

Information should be given in terms that the patient can understand. The physician should be sensitive to the patient's responses in setting the pace of communication, particularly if the illness is very serious. Disclosure and the communication of health information should never be a mechanical or perfunctory process. Upsetting news and information should be presented to the patient in a way that minimizes distress (31). If the patient cannot comprehend his or her condition, it should be fully disclosed to an appropriate surrogate.

Therapeutic nondisclosure, also called "therapeutic privilege," is the withholding of relevant health information from the patient if disclosure is believed to be medically contraindicated (32). Because this exception could swallow the rule of informed consent, therapeutic privilege should be rarely invoked and only after consultation with a colleague. A thorough review of the benefits and harms to the patient and ethical justification of nondisclosure is required (33).

In addition, physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.

Informed Decision Making and Consent

Truly informed decision making is patient-centered. The patient's consent allows the physician to provide care. The unauthorized touching of a person is battery, even in the medical setting. Consent may be either expressed or implied. Expressed consent most often occurs in the hospital setting, where patients provide written or oral consent for a particular procedure. In many medical encounters, when the patient presents for evaluation and care, consent can be implied. The underlying condition and treatment options are explained to the patient or authorized surrogate and treatment is rendered or refused. In medical emergencies, consent to treatment necessary to maintain life or restore health is usually presumed unless it is known that the patient would refuse the intervention.

The doctrine of informed consent goes beyond the question of whether consent was given. Rather, it focuses on the content and process of consent. The physician must provide enough information for the patient to make an informed judgment about how to proceed. The physician's presentation should include an assessment of the patient's understanding, be balanced, and include the physician's recommendation. Decision aids may be useful supplements. The patient's (or surrogate's) concurrence must be free and uncoerced.

The principle and practice of informed consent rely on patients to ask questions when they are uncertain about the information they receive; to think carefully about their choices; and to be forthright with their physicians about their values, concerns, and any reservations about a particular recommendation. The question to the patient, "What questions do you have?" may be

more respectful and useful than the question, "Do you have any questions?" Once patients and physicians decide on a course of action, patients should make every reasonable effort to carry out the aspects of care under their control or inform their physicians promptly if it is not possible to do so.

The physician must ensure that the patient or the surrogate is adequately informed about the nature of the patient's medical condition and the objectives of, alternatives to, possible outcomes of, and risks of a proposed treatment.

Competence is a legal determination. All adult patients are considered competent to make decisions about medical care unless a court has declared them incompetent. In clinical practice, however, physicians and family members usually make decisions without a formal competency hearing in the court for patients who lack decision-making capacity (that is, the ability to receive and express information and to make a choice consonant with that information and one's values). This clinical approach can be ethically justified if the physician has assessed decision-making capacity and determined that the patient is incapable of understanding the nature of the proposed treatment; the alternatives to it; and the risks, benefits, and consequences of it. Assessing a patient's understanding can be difficult. Decision-making capacity should be evaluated for a particular decision at a particular point in time. The capacity to express a particular goal or wish can exist without the ability to make more complex decisions. The greater the consequences of the decision, the more important the assessment of decision-making capacity.

When a patient lacks decision-making capacity, an appropriate surrogate should make decisions with the physician. Treatment should conform to what the patient would want on the basis of written or oral advance care planning. If these preferences are not known, care decisions should be based on the best evidence of what the patient would have chosen based on the patient's values, previous choices, and beliefs (substituted judgments) or, failing that, on the best interests of the patient. However, there may be situations in which best-interest decisions should supersede substituted judgments (34).

If the patient has designated a proxy, as through a durable power of attorney for health care, that choice should be respected. In the absence of a formal appointment of a health care agent, some states have health care consent statutes that specify who and in what order of priority family members or close others can serve as surrogates. When patients have not selected surrogates, a family member—which could be a domestic partner—should serve as surrogate. Physicians should be aware of legal requirements in their states for surrogate appointment and decision making. In some cases, all parties may agree that a close friend is a more appropriate surrogate than a relative.

Surrogate preferences can conflict with the preferences and best interests of a patient. Physicians should take reasonable care to ensure that the surrogate's de-

cisions are consistent with patient preferences and best interests. When possible, these decisions should be reached in the medical setting. Physicians should emphasize to surrogates that decisions should be based on what the patient would want, not what surrogates would choose for themselves. Hospital ethics committees can be valuable resources in difficult situations. Courts should be used when doing so serves the patient, such as to establish guardianship for an unbefriended incompetent patient, to resolve a problem when other processes fail, or to comply with state law.

Physicians should routinely encourage patients to discuss their future wishes with appropriate family and friends and complete a living will and/or durable power of attorney for health care (35) (see also the Advance Care Planning section in Care of Patients Near the End of Life).

Most adult patients can participate in, and thereby share responsibility for, their health care. Physicians cannot properly diagnose and treat conditions without full information about the patient's personal and family medical history, habits, ongoing treatments (medical and otherwise), and symptoms. The physician's obligation of confidentiality exists in part to ensure that patients can be candid without fear of loss of privacy.

Physicians must strive to create an environment in which honesty can thrive and patients feel that concerns and questions are elicited.

Decisions About Reproduction

The ethical duty to disclose relevant information about human reproduction to the patient may conflict with the physician's personal moral standards on abortion, sterilization, contraception, or other reproductive services. A physician who objects to these services is not obligated to recommend, perform, or prescribe them. However, the physician has a duty to inform the patient about care options and alternatives or refer the patient for such information, so that the patient's rights are not constrained. Physicians unable to provide such information should transfer care as long as the health of the patient is not compromised.

If a patient who is a minor requests termination of pregnancy, advice on contraception, or treatment of sexually transmitted diseases without a parent's knowledge or permission, the physician may wish to attempt to persuade the patient of the benefits of having parents involved, but should be aware that a conflict may exist between the legal duty to maintain confidentiality and the obligation toward parents or guardians. Information should not be disclosed to others without the patient's permission (25). In such cases, the physician should be guided by the minor's best interest in light of the physician's conscience and responsibilities under the law.

Precision Medicine, Genetic Testing, Privacy, and Confidentiality

Precision medicine is an approach to disease treatment, prevention, and risk stratification that takes into account individual variability in genes, environment, and lifestyle. The goal is to promote more accurate di-

agnosis and personalized management of health and disease. It includes the following types of testing: predictive genomic testing done in asymptomatic individuals to determine whether an individual is at increased risk for disease; diagnostic testing done to rule out or confirm the suspicion of a genetic condition, based on clinical characteristics in an already affected individual; pharmacogenomics testing to guide medication prescribing; molecular profiling of tumors to guide therapeutic decisions; and whole-genome sequencing to assess an entire genome for genetic mutations that may cause disease (36).

Precision medicine raises issues of patient and physician education, counseling, privacy, confidentiality, cost, the patient's best interests, and justice. Genomic testing may predict diseases or detect susceptibility without the ability to prevent, treat, or cure the conditions identified. It presents unique challenges by identifying disease risk not only for patients, but also for family members, who may not be aware of or interested in obtaining information on their risk for disease. Also, the public and health care professionals often have a limited understanding of the distinction between prediction and susceptibility or risk.

Advances in genomics and the advent of direct-to-consumer personal genomic testing are likely to result in an increased number of patients inquiring about genomic testing and requesting that clinicians interpret genomic test results (37). Because the number of qualified clinical geneticists and genetic counselors is small and is unlikely to meet the demand generated by the growth in genetic testing, clinicians will be increasingly expected to counsel patients before testing and interpret genetic test results. Before undergoing a genomic test, patients should understand the benefits, risks, limitations, and possible consequences of genomic testing. If a clinician is not qualified to engage patients in a pretest process of informed consent for genomic testing or does not have the knowledge to interpret the results of a genomic test, the clinician should refer the patient to a clinical geneticist or genetic counselor.

Before offering a genomic test, clinicians should consider the following test characteristics:

1. Analytical validity—whether the test accurately detects the presence or absence of a mutation.
2. Clinical validity—whether the test accurately relates the mutation to the disease.
3. Clinical utility—whether the results will inform the diagnosis, treatment, or prevention of a disease.
4. Personal utility—whether the results will provide patients with important personal or familial information to inform decision making.

The risks, benefits, limitations, and cost of testing should be made clear to patients in advance of testing. The possibility of uncovering information with uncertain disease associations or incidental to the reason for testing; potential anxiety or other impact on the patient's well-being; implications for family members; and the potential for labeling or adverse use of such information by employers, insurers, or other societal institutions should

Box 5. Precision medicine and genetics.

Precision medicine raises issues of patient and physician education, counseling, privacy, confidentiality, cost, the patient's best interests, and justice.

Genomic testing may predict diseases or detect susceptibility without the ability to prevent, treat, or cure the conditions identified and present unique challenges by identifying disease risk not only for patients, but also for family members, who may not be aware of or interested in obtaining information on their risk for disease.

The public and health care professionals often have a limited understanding of the distinction between prediction and susceptibility or risk.

Because the number of qualified clinical geneticists and genetic counselors is small and is unlikely to meet the demand generated by the growth in genetic testing, clinicians will be increasingly expected to counsel patients before testing and interpret genetic test results. Before undergoing a genomic test, patients should understand the benefits, risks, limitations, and possible consequences of genomic testing. If a clinician is not qualified to engage patients in a pretest process of informed consent for genomic testing or does not have the knowledge to interpret the results of a genomic test, the clinician should refer the patient to a clinical geneticist or genetic counselor.

Prior to offering a genomic test, clinicians should consider the following test characteristics:

Analytical validity: whether the test accurately detects the presence or absence of a mutation

Clinical validity: whether the test accurately relates the mutation to the disease

Clinical utility: whether the results will inform the diagnosis, treatment or prevention of a disease

Personal utility: whether the results will provide patients with important personal or familial information to inform decision making

The risks, benefits, limitations, and cost of testing should be made clear to patients in advance of testing. The possibility of uncovering information with uncertain disease associations or incidental to the reason for testing; potential anxiety or other impact on the patient's well-being; implications for family members; and the potential for labeling or adverse use of such information by employers, insurers, or other societal institutions should be fully explored and understood.

Testing should not be undertaken until the potential consequences of learning genetic information are fully discussed with the patient. For these and other reasons, patients should be aware that personal genomic direct-to-consumer testing should be approached with caution.

Physicians should inform patients of genetic privacy risks and implications for themselves and family members, so that patients are able to make a well-informed decision about testing and disclosure of genetic information.

be fully explored and understood. Testing should not be undertaken until the potential consequences of learning genetic information are fully discussed with the patient (38). For these and other reasons, patients should be aware that personal genomic direct-to-consumer testing should be approached with caution.

Knowledge of genetic susceptibility to a disease may substantially alter the lives of individuals and their families, with implications for employment, life, disability or long-term care insurance coverage, childbearing, diet, and familial relationships. Although information about the presence of susceptibility to a genetic disease or the presence of a genetic disease in a family member raises the possibility that genetically related individuals are at risk, the primary obligation of the physician is to promote the best interests of the patient. However, the physician should encourage the patient's cooperation in contacting family members at risk or obtain the patient's consent to recommend consideration of genetic counseling.

As more information becomes available on genetic risk for certain diseases, physicians must be aware of the need for confidentiality concerning genetic information and should follow best practices to minimize the potential for unauthorized or inappropriate disclosure of genomic data (39). Complex ethical problems

exist, such as which family member should be informed of the results of genomic tests. Physicians should be sensitive to these issues, and testing should not be undertaken until the issues are fully discussed and their consequences are well understood. Other concerns related to genetic privacy include discrimination; cultural considerations; the ability to safeguard genetic data; and the potential for identifying patients through unauthorized methods, including potential access by law enforcement agencies without first obtaining a warrant (40). Many state governments and the federal government are promulgating rules on access of employers and insurers to such information. The Genetic Information Nondiscrimination Act of 2008 was designed to prevent discrimination in health insurance and employment based on genetic information. Physicians should inform patients of genetic privacy risks and implications for themselves and family members, so that patients are able to make a well-informed decision about testing and disclosure of genetic information.

Guidance on ethical issues in precision medicine and genetics is noted in **Box 5**.

Medical Risk to Physician and Patient

Physicians take an oath to serve the sick. Traditionally, the ethical imperative for physicians to provide

care has overridden the risk to the treating physician, even during epidemics. In recent decades, with better control of such risks, physicians have practiced medicine in the absence of risk as a prominent concern. However, potential occupational exposures, such as Ebola virus disease, Zika virus, HIV, multidrug-resistant tuberculosis, and severe acute respiratory syndrome necessitate reaffirmation of the ethical imperative (41).

Physicians' ethical obligation to the welfare of patients is a fundamental tenet of the medical profession. The social contract between medicine and society also requires physicians to treat all in need of care. Physicians should evaluate their risk for becoming infected with pathogens, both in their personal lives and in the workplace, and implement appropriate precautions, including following guidelines for hygiene, protective garb, immunization, and constraints for exposure, designed to decrease spread of infection. Physicians who may have been exposed to pathogens have an ethical obligation to be tested and voluntarily quarantine themselves to limit the potential risk to society. Infected physicians should place themselves under the guidance of their personal physician or the review of local experts to determine in a confidential manner whether practice restrictions are appropriate on the basis of the physician's specialty, compliance with infection-control precautions, and physical and mental fitness to work. Infection does not in itself justify restrictions on the practice of an otherwise competent clinician. Physicians are expected to comply with public health and institutional policies.

Because the diseases mentioned above may be transmitted from patient to physician and pose risks to physicians' health, some physicians may be tempted to avoid the care of infected patients. Physicians and health care organizations are obligated to provide competent and humane care to all patients, regardless of their illness (42). Physicians can and should expect their workplace to provide appropriate means to limit occupational exposure through rigorous infection-control methods. The denial of appropriate care to a class of patients for any reason, including disease state, is unethical.

Whether infected physicians should disclose their condition depends on the likelihood of risk to the patient and relevant law or regulations. Physicians should remove themselves from care if it becomes clear that the risk associated with contact or with a procedure is high despite appropriate preventive measures. Physicians are obligated to disclose their condition after the fact if a clinically significant exposure has taken place.

Physicians have several obligations concerning nosocomial risk for infection. They should help the public understand the low level of this risk and put it in the perspective of other medical risks while acknowledging public concern. Physicians provide medical care to health care workers, and part of this care is discussing with them the duty to know their risk for such diseases as Ebola or HIV, to voluntarily seek testing if they are at risk, and to take reasonable steps to protect patients. The physician who provides care for a potentially infec-

tious health care worker must determine that worker's fitness to work. In some cases, potentially infectious health care workers cannot be persuaded to comply with accepted infection-control guidelines. In such exceptional cases, the treating physician may need to breach confidentiality and report the situation to the appropriate authorities in order to protect patients and maintain public trust in the profession, even though such actions may have legal consequences.

The Patient–Physician Relationship and Health Care System Catastrophes

Large-scale health catastrophes from infectious causes (for example, Ebola, influenza, severe acute respiratory syndrome), natural disasters (for example, tsunamis, earthquakes, hurricanes), or terrorist attacks can overwhelm the capabilities of health care systems and have the potential to stress and even change the traditional norms of the patient-physician relationship. For example, physicians may unavoidably conduct triage. Furthermore, many state, national, and international bodies have issued reports on health catastrophes that include recommendations for unilateral physician decisions to withhold and withdraw mechanical ventilation from some patients who might still benefit from it, when the demand for ventilators exceeds supply (43–46). The guiding principles for health care delivery during catastrophes may shift from autonomy and beneficence to utility, fairness, and stewardship. One report notes that “[a] public health disaster such as an influenza pandemic, by virtue of severe resource scarcity, imposes harsh limits on decision-making autonomy for patients and health care providers” (43). Physicians together with public and governmental organizations should participate in the development of guidelines for the just delivery of health care in times of catastrophe, being mindful of existing health disparities that may affect populations or regions.

Complementary and Integrative Care

Complementary and integrative health involves bringing health care approaches developed outside of mainstream Western medicine to conventional approaches to health (47). Folk healing practices are also common in many cultures. In 2012, 33% of U.S. adults reported using complementary and integrative approaches, and out-of-pocket spending for complementary health approaches represented 9.2% of all out-of-pocket spending on health care and 1.1% of total health care spending (48).

Patients may value the differing approaches of Western medicine, with its scientific basis, and complementary medicine. A failure of conventional therapy, or cultural concerns, might lead a patient to alternative approaches to care. Requests by patients for alternative treatment require balancing the medical standard of care with a patient's right to choose care on the basis of his or her values and preferences. Such requests warrant careful physician attention. Before advising a patient, the physician should ascertain the reason for the request. The physician should be sure that the patient understands his or her condition, standard medical

treatment options, and expected outcomes. Because most patients do not affirmatively disclose their use of complementary approaches, physicians should ask patients about their current practices (49, 50) as an essential part of a complete history.

The physician should encourage the patient who is using or requesting alternative treatment to seek literature and information from reliable sources (51). The patient should be clearly informed if the option under consideration is likely to delay access to effective treatment or is known to be harmful. The physician and patient should be aware of the potential impact of complementary medicine on the patient's care. Interactions between complementary therapies and conventional medications are common and should be discussed with patients. Physicians should not dismiss complementary approaches to medical care because it may impair communication and the therapeutic relationship with patients. The patient's decision to select alternative forms of treatment should not alone be cause to sever the patient-physician relationship.

Disability Certification

Some patients have chronic, overwhelming, or catastrophic illnesses. In these cases, society permits physicians to justify exemption from work and to legitimize other forms of financial support. As patient advocate, a physician may need to help a medically disabled patient obtain the appropriate disability status. Disability evaluation forms should be completed factually and promptly.

A physician may see a patient whose problems do not fit standard definitions of disability but who nevertheless seems deserving of assistance. As in all circumstances, physicians must act honestly. They should not distort medical information or misrepresent the patient's functional status in an attempt to help patients. Doing so jeopardizes the trustworthiness of the physician, as well as his or her ability to advocate for patients who truly meet disability or exemption criteria.

Providing Medical Care to One's Self; Persons With Whom the Physician Has a Preexisting Close Nonprofessional Relationship or a Reporting Relationship; and VIPs

Physicians may want to provide care for themselves, or from time to time be asked to provide medical care to a family member or others with whom the physician has a close nonprofessional relationship or an employee or supervisor with whom there is a reporting relationship. Each of these situations raises clinical and professionalism concerns that should be considered.

Except in emergent circumstances when no other option exists, physicians ought not care for themselves. A physician cannot adequately interview, examine, or counsel herself or himself, without which ordering diagnostic tests, medications, or other treatments is ill-advised.

Regarding people with whom the physician has a significant preexisting, nonprofessional relationship, such as family members and close friends, and regarding employees or supervisors, the relationship neces-

sarily adds another layer that may complicate what would become the professional patient-physician relationship. While the patient may feel unduly restrained in making choices, or inhibited in speaking about certain matters or in rejecting physician recommendations, the physician may be unduly impaired in maintaining clinical objectivity; inadequate history-taking or physical examination, overtesting, inappropriate prescribing, incomplete counseling on sensitive issues, or failure to keep appropriate medical records are also potential issues. The needs of the patient may not fall within the physician's area of expertise, and emotional proximity may result in difficulties for the patient and/or the physician (52, 53). A physician in these circumstances, however, could serve as an advisor or medical interpreter and suggest questions to ask, explain medical terminology, accompany the patient to appointments, and help advocate for the patient. Alternatively, the physician could use his or her knowledge or contacts to refer the person to another physician.

Given the complexity and possible risks, physicians should usually not enter into these dual relationships. If they do assume such care after weighing concerns, all possible alternatives, and seeking counsel from colleagues, they should do so with the same comprehensive diligence and careful documentation as exercised with any other patient. Whenever physicians provide medical care, they should do so only within their realm of expertise. Medical records should be kept just as for any other patient.

Taking care of very important persons (VIPs) poses different challenges. The physician should avoid the tendency to skip over sensitive portions of the relevant medical history or physical examination. As with other patients, fame or prestige ought not buy patients medical care that is not medically indicated. Patient privacy and confidentiality must be protected, as for all patients (see the Confidentiality section). The social standing of a VIP should not negatively affect the physician's responsibilities toward other patients (54).

Sexual Contact Between Physician and Patient

Issues of dependency, trust, transference, and inequalities of power lead to increased vulnerability on the part of the patient and require that a physician not engage in a sexual relationship with a patient. It is unethical for a physician to become sexually involved with a current patient even if the patient initiates or consents to the contact.

Sexual involvement between physicians and former patients also raises concern. The impact of the patient-physician relationship may be viewed very differently by physicians and former patients, and either may underestimate the influence of the past professional relationship. Many former patients continue to feel dependency and transference toward their physicians long after the professional relationship has ended. The intense trust often established between physician and patient may amplify the patient's vulnerability in a subsequent sexual relationship. A sexual relationship with a former patient is unethical if the physician uses or

exploits the trust, knowledge, emotions, or influence derived from the previous professional relationship (55). Because it may be difficult to judge the impact of the previous professional relationship, the physician should consult with a colleague or other professional before becoming sexually involved with a former patient (56).

Boundaries and Privacy

In certain circumstances, the presence of a chaperone during a physical examination may contribute to patient and physician comfort because of particular cultural or gender issues. In appropriate situations, physicians should communicate the reasons for the use of chaperones and any institutional or legal requirements, asking patients whether they prefer to have a chaperone present. Because most physician offices do not regularly employ chaperones, the person who is asked to perform this role is temporarily relieved of his or her other responsibilities to accommodate this request. In offices where resources are limited, such reassignments can lead to interruption of workflow. Patients may view the presence of another person in the examination room as an intrusion into their privacy. In general, the more intimate the examination, the more the physician is encouraged to offer the presence of a chaperone. Discussion of confidential patient information must be kept to a minimum during chaperoned examinations. Family members of the patient should not act as chaperones.

Physicians who use online media, such as social networks, blogs, and video sites, should be aware of the potential to blur social and professional boundaries. They therefore must be careful to extend standards for maintaining professional relationships and confidentiality from the clinic to the online setting and “pause before posting” to reflect upon what the public and colleagues might think about the online content. Physicians must remain cognizant of the privacy settings for secure messaging and recording of patient-physician interactions, as well as online networks and media, and should maintain a professional online demeanor (15, 57).

Gifts From Patients

In deciding whether to accept a gift from a patient, the physician should consider the nature of the gift and its value to the patient, the potential implications for the patient-physician relationship of accepting or refusing it, and the patient's possible intention and expectations (58). A small gift as a token of appreciation usually is not ethically problematic. Favored treatment as a result of acceptance of any gift is problematic and undermines professionalism. It may also interfere with objectivity in the care of the patient (59). Physician involvement in patient or family gifts to an institution can raise ethical issues for the patient-physician relationship and confidentiality (60). Donations should be explored with the institution's administration.

CARE OF PATIENTS NEAR THE END OF LIFE

Physicians and the medical community must be committed to the compassionate, timely, and competent provision of care to dying patients and their families and effective communication with patients and families (35, 61). Patients rightfully expect their physicians to care for them as they live with eventually fatal illnesses. Good symptom control; ongoing commitment to serve the patient and family; and physical, psychological, and spiritual support are the hallmarks of high-quality end-of-life and hospice care. Care of patients near the end of life, however, has a moral, psychological, and interpersonal intensity that distinguishes it from most other clinical encounters. It is the physician's professional obligation to develop and maintain competency in end-of-life care.

Palliative Care

Although palliative care may benefit any patient with serious illness, palliative care for dying patients should address physical, psychosocial, and spiritual needs and at times may be required in an acute care context (62-64). To provide palliative care, the physician must be up to date on the proper use of medications and treatments, including the ethical and legal basis of the use of opioids as necessary to relieve pain. The physician should seek appropriate palliative care consultation when doing so is in the patient's best interest, know when and how to use home-based and institution-based hospice care, and be aware of the palliative care capabilities of nursing homes to which patients are referred. Physicians should be guided by data on the benefits of early initiation of palliative care and should improve timelier appropriate referrals to hospice. Patients and families often do not know what hospice or palliative care is but say they want it when informed about this type of care (64).

Clinicians should prepare the patient and family for the course of illness and care options (65). Cultural differences at the end of life, including differences in beliefs and values, should be respected by physicians (30). Clinicians should also assist family members and loved ones experiencing grief after the patient's death in receiving bereavement support.

Physicians should partner with colleagues from social work, chaplaincy, and other fields to meet psychosocial, spiritual, and other needs of dying patients and their families. Palliative care chaplains frequently attend medical rounds, assist with goals of care discussions, and aid patients experiencing spiritual distress (66).

Making Decisions Near the End of Life

Informed adults with decision-making capacity have the legal and ethical right to refuse recommended life-sustaining medical treatments. This includes any medical intervention, including ventilators, artificial nutrition and hydration, and cardiovascular implantable electronic devices (such as pacemakers and implantable cardioverter-defibrillators) (67). The patient's right to refuse treatment is based on the philosophical and ethical concept of respect for autonomy, the common-

Table 2. Advance Care Planning and Surrogate Decision Making

Action	Description
Raise advance care planning before an acute crisis	Physicians should routinely raise advance care planning with adult patients with decision-making capacity and encourage them to review their values and preferences for future care with their surrogates and family members.
Document care preferences	Conversations with the patient and patient views about care preferences should be documented in the medical record. Written advance directives include living wills and the durable power of attorney for health care for appointing a surrogate to make decisions if the patient becomes unable to do so.
Assist surrogate decision makers in fulfilling their responsibilities	The surrogate is obligated to act in accordance with patient's previously expressed preferences or best interests. Some patients want their surrogates to strictly adhere to their expressed wishes. Others want their surrogates to have flexibility in decision making. Patients should specify what authority and discretion in decision making they are giving their surrogates.

law right of self-determination, and the patient's liberty interest under the U.S. Constitution (68). This right exists, regardless of whether the patient is terminally or irreversibly ill, has dependents, or is pregnant. When a physician disagrees with a patient's treatment decisions, the physician should respond with empathy and thoughtful exploration of all appropriate possibilities, including time-limited trials and additional consultation. If the patient's or family's treatment decisions violate the physician's sense of professional integrity, referral to another qualified physician may be considered, but the patient and family should not be abandoned. Consultation with an ethics committee can be of assistance in mediating such disputes.

Patients without decision-making capacity (see the Informed Decision Making and Consent section) have the same rights concerning life-sustaining treatment decisions as mentally competent patients and can make their wishes known through written or oral advance care planning. If these preferences are not known, care decisions should be based on the best evidence of what the patient would have chosen, based on the patient's values, previous choices, and beliefs (substituted judgments) or, failing that, on the best interests of the patient. However, there may be situations in which best-interest decisions should supersede substituted judgments (34). Physicians should be aware that hospital protocols and state legal requirements affecting end-of-life care vary. Patients with mental illness may pose particular challenges in understanding their wishes regarding end-of-life care. The presence of mental illness is not *prima facie* evidence of decisional incapacity. Psychiatric consultation should be considered to explore the patient's ability to participate in decision making.

Advance Care Planning

Advance care planning allows a person with decision-making capacity to develop and indicate preferences for treatment and choose a surrogate to act on his or her behalf in the event that he or she cannot make health care decisions. It allows the patient's values and circumstances to shape the plan with specific arrangements for implementation of the plan.

Physicians should routinely raise advance planning with adult patients with decision-making capacity and encourage them to review their values and preferences with their surrogates and family members (Table 2). This is often best done in the outpatient setting before an acute crisis. These discussions let the physician know the patient's views, enable documentation of patient wishes in the medical record, and allow the physician to reassure the patient that he or she is willing to discuss these sensitive issues and will respect patient choices. The Patient Self-Determination Act of 1990 requires hospitals, nursing homes, health maintenance organizations, and hospices that participate in Medicare and Medicaid to ask whether the patient has an advance directive, to provide information about advance directives, and to incorporate them into the medical record. It does not require completion of an advance directive as a condition of care.

Written advance directives include living wills and durable powers of attorney for health care. The latter enables a patient to appoint a surrogate to make treatment decisions if the patient becomes unable to do so. The surrogate is obligated to act in accordance with the patient's previously expressed preferences or best interests. Some patients want their surrogates to adhere strictly to their expressed wishes. Others, however, want their surrogates to have flexibility in decision making (69–71). Patients should specify what authority and discretion in decision making they are giving their surrogates.

Living wills enable individuals to describe the treatment they would like to receive in the event that decision-making capacity is lost. Uncertainty about a future clinical course complicates the interpretation of living wills and emphasizes the need for physicians, patients, and surrogates to discuss patient preferences before a crisis arises. Some state laws limit the application of advance directives, for example to terminal illness, or deem advance directives not applicable for pregnant patients. Requirements for witnessing documents vary.

Advance directives should be readily accessible to health care professionals regardless of the site of care. When there is no advance directive and the patient's values and preferences are unknown or unclear, decisions should be based on the patient's best interests, as interpreted by a guardian or a person with personal knowledge of the patient, if available. When making the decision to forgo treatment, many people give the most weight to reversibility of disease or dependence on life support, loss of capacity for social interaction, or nearness to death. Family members and clinicians should avoid projecting their own values or views about quality of

life onto the incapacitated patient. Quality of life should be assessed according to the patient's perspective (72, 73).

Withdrawing or Withholding Treatment

Withdrawing and withholding treatment are equivalent, ethically and legally, although state evidentiary standards for and cultural and religious beliefs about withdrawing or withholding treatment may vary. Treatments should not be withheld because of the mistaken fear that if they are started, they cannot be withdrawn. This would deny patients potentially beneficial therapies. Instead, a time-limited trial of therapy could be used to clarify the patient's prognosis. At the end of the trial, a conference to review and revise the treatment plan should be held. Some family members may be reluctant to withdraw treatments even when they believe that the patient would not have wanted them continued. The physician should try to prevent or resolve these situations by addressing with families feelings of guilt, fear, and concern that the patient may suffer as life support is withdrawn, ensure that appropriate measures to relieve distress are used, and explain the physician's ethical obligation not to impose unwanted treatment on the patient.

Artificial Nutrition and Hydration

Artificial administration of nutrition and fluids is a medical intervention subject to the same principles of decision making as other treatments. Some states require high levels of proof of the patient's specific wishes regarding artificial nutrition or hydration. Physicians should counsel patients desiring to forgo artificial nutrition and hydration under some circumstances to include this in an advance directive. Despite research to the contrary, concerns remain that discontinuing feeding tubes will cause suffering from hunger or thirst (74). On the other hand, imminently dying patients may develop fluid overload as their kidneys stop functioning, with peripheral and pulmonary edema; continued administration of intravenous fluids exacerbates these symptoms and may cause substantial distress. Physicians should address these issues with patients and loved ones involved in the patient's care.

Do-Not-Resuscitate Orders

A do-not-resuscitate order (DNR order)—or do-not-attempt-resuscitation order (DNAR order) or allow natural death order (AND order)—is a physician order to forgo basic cardiac life support in the outpatient setting and advanced cardiac life support in the inpatient setting. Intervention in the case of a cardiopulmonary arrest is inappropriate for some patients, particularly those for whom death is expected, imminent, and unavoidable. Because the onset of cardiopulmonary arrest does not permit deliberative decision making, decisions about resuscitation must be made in advance. Physicians should especially encourage patients who face serious illness or who are of advanced age (or their surrogates as appropriate) to discuss resuscitation.

A DNR order applies only to cardiopulmonary resuscitation. Discussions about this issue may reflect a

revision of the larger goals and means of the care plan, and the extent to which a change is desired in treatment goals or specific interventions must be explicitly addressed for each patient. A DNR order must be documented in the medical record along with notes and orders that describe all other changes in the treatment goals or plans, enabling the entire health care team to understand and act in accord with that plan. A DNR order does not mean that the patient is ineligible for other potentially life-prolonging measures, therapeutic and palliative. Because they are deceptive, half-hearted resuscitation efforts ("slow codes") should not be performed (75).

A patient who is a candidate for intubation but declines will develop respiratory failure and is expected to experience cardiac arrest. For this reason, physicians should not write a do-not-intubate order in the absence of a DNR order. Moreover, it is important to address the patient's or surrogate's wishes regarding intubation and intensive care unit transfer in tandem with discussions about resuscitation.

A DNR order should not be suspended simply because of a change in the venue of care. When a patient with a preexisting DNR order is to undergo, for example, an operative procedure requiring general anesthesia, fiberoptic bronchoscopy, or gastroesophageal endoscopy, the physician should discuss the rationale for continuing or temporarily suspending the DNR order. This change in DNR status requires the consent of the patient or appropriate surrogate decision maker.

In general, any decision about advance care planning, including a decision to forgo attempts at resuscitation, applies in other care settings for that patient, and this should be routinely addressed. Many states and localities have systematic requirements for out-of-hospital implementation of DNR orders (76). Physicians should know how to effectuate the order and try to protect the patient from inappropriate resuscitation efforts. Physicians should ensure that DNR orders transfer with the patient and that the subsequent care team understands the basis for the decision.

Futile Treatments

In the circumstance that a specific treatment desired by the patient or family is medically ineffective and potentially harmful, the physician is not ethically obliged to provide such treatment (although the physician should be aware of any relevant state law). The physician need not provide an effort at resuscitation that cannot conceivably restore circulation and breathing, but he or she should help the family to understand and accept this reality. The more common and much more difficult circumstance occurs when treatment offers some small prospect of benefit at a great burden of suffering (or financial cost—see the Resource Allocation section in the Physician and Society), but the patient or family nevertheless desires it. If the physician and patient (or appropriate surrogate) cannot agree on how to proceed, there is no easy, automatic solution. Consultation with learned colleagues or an ethics consultation may be helpful in ascertaining what interventions have

a reasonable balance of burden and benefit. Timely transfer of care to another clinician who is willing to pursue the patient's preference may resolve the problem. Infrequently, resort to the courts may be necessary. Some jurisdictions have specific processes and standards for allowing these unilateral decisions.

Some institutions allow physicians to unilaterally write a DNR order over patient or family objections when the patient may survive, at most, for only a brief time in the hospital. Empathy and thoughtful exploration of options for care with patients or surrogate decision makers should make such impasses rare. Full discussion about the issue should include the indications for and outcomes of cardiopulmonary resuscitation, the physical impact on the patient, the implications for clinicians, the impact (or lack thereof) of a DNR order on other care, the legal aspects of such orders, and the physician's role as patient advocate. A physician who writes a unilateral DNR order must inform the patient or surrogate and give a detailed explanation when doing so.

Determination of Death

The irreversible cessation of all functions of the entire brain is an accepted legal standard for determining death when the use of life support precludes reliance on traditional cardiopulmonary criteria. After a patient has been declared dead by brain-death criteria, medical support should ordinarily be discontinued. In some circumstances, such as the need to preserve organs for transplantation or to counsel or accommodate family beliefs or needs, physicians may temporarily support bodily functions after death has been determined. In the case of a pregnant, brain-dead patient, efforts to perfuse the body in order to support the fetus should be undertaken only after careful deliberation about the patient's interests and previous wishes, if known.

Physician-Assisted Suicide and Euthanasia

Physician-assisted suicide occurs when a physician provides a medical means of death, usually a prescription for a lethal amount of medication that the patient takes on his or her own. In euthanasia, the physician directly and intentionally administers a substance to cause death. Six states and the District of Columbia have legalized the practice of physician-assisted suicide in the United States (77). Many other states have had referenda and legislative proposals on both sides of the issues.

A decision by a patient or authorized surrogate to refuse life-sustaining treatment or an inadvertent death during an attempt to control pain should be distinguished from physician-assisted suicide and euthanasia. Laws concerning or moral objections to physician-assisted suicide and euthanasia should not deter physicians from honoring a decision to withhold or withdraw medical interventions as appropriate. Fears that unwanted life-sustaining treatment will be imposed continue to motivate some patients to request assisted suicide or euthanasia.

In the clinical setting, all of these acts must be framed within the larger context of good end-of-life

care. Some patients who request assisted suicide may be depressed or have uncontrolled pain. In providing comfort to a dying person, most physicians and patients should be able to address these issues. For example, regarding pain control, the physician may appropriately increase medication to relieve pain, even if this action inadvertently shortens life (78, 79). In Oregon, for example, losing autonomy or dignity and inability to engage in enjoyable life activities have been cited as concerns in most physician-assisted suicide cases (80). These concerns are less amenable to the physician's help, although physicians should be sensitive to these aspects of suffering.

The College does not support legalization of physician-assisted suicide or euthanasia (77). After much consideration, the College concluded that making physician-assisted suicide legal raised serious ethical, clinical, and social concerns. The major emphasis of the College and its members, including those who lawfully participate in the practice, should be ensuring that all persons can count on good care through to the end of life, with prevention or relief of suffering insofar as possible, an unwavering commitment to human dignity and relief of pain and other symptoms, and support for family and friends. Physicians and patients must continue to search together for answers to the problems posed by the difficulties of living with serious illness before death, neither violating the physician's personal and professional values, nor abandoning the patient.

Disorders of Consciousness

There are a variety of disorders of impaired consciousness with variable prognoses, including coma, persistent and permanent irreversible vegetative states ("wakeful unresponsiveness"), and the minimally conscious state (81). Before making ethical judgments about appropriate care, it is critical that qualified clinicians provide diagnostic clarity in determining the patient's brain state (82). Goals of care as decided by the patient in advance or by an appropriate surrogate should guide decisions about treatment for these patients as for other patients without decision-making capacity.

Solid Organ Transplantation

All patients should be encouraged to communicate their preference for or against organ donation to their families as well as have it listed on such documents as advance directives, driver's licenses, or organ donor cards. Ideally, physicians will discuss the option of organ donation with patients during advance care planning as part of a routine office visit, before the need arises (83).

Organ donation requires consideration of several issues. One set of concerns is the need to avoid even the appearance of conflict between the care of a potential donor and the needs of a potential recipient (84). The care of the potential donor must be kept separate from the care of a recipient. The potential donor's physician should not be responsible for the care of the recipient or be involved in retrieving the organs or tissue.

Under federal regulations, all families must be presented with the option of organ donation when the death of the patient is imminent. To avoid conflicts of interest, neither physicians who will perform the transplantation nor those caring for the potential recipient should make the request. Physicians caring for the potential donor should ensure that families are treated with sensitivity and compassion. Previously expressed preferences about donation by dying or brain-dead patients should be sought and respected. Only organ procurement representatives who have completed training by an organ procurement organization may initiate the actual request (85).

Another set of issues involves the use of financial incentives to encourage organ donation. While increasing the supply of organs is a noble goal, the use of direct financial incentives raises ethical questions related to treating humans as commodities and the potential for exploitation of vulnerable individuals and families. Even the appearance of exploitation may ultimately be counterproductive to the goal of increasing the pool of organs.

Before declaration of brain death, treatments or interventions proposed to maintain the function of transplantable organs may be used only if they are not expected to harm the potential donor. In the case of brain-dead donors, once organ donation is authorized, the donor's physician should know how to maintain the viability of organs and tissues in coordination with the procurement team.

A particular set of issues has been raised by the advent of "donation after circulatory death" (previously known as "non-heart-beating cadaveric organ donation"). This approach allows patients who do not meet the criteria for brain death but for whom a decision has been made to discontinue life support to be considered potential organ donors. Life support is discontinued under controlled conditions. Once cardiopulmonary criteria for death are met, and a suitable period of time has elapsed that ensures clinical certitude of death but does not unduly compromise the chances of successful transplantation (generally 2 to 5 minutes), the organs are procured. This generally requires that the still-living patient be moved to the operating room (or nearby suite) in order to procure the organs as quickly after death as possible.

As in organ donation from brain-dead individuals, the care of the potential donor after circulatory death and the request from the family must be separated from the care of the potential recipient. The decision to discontinue life support must be kept separate from the decision to donate, and the actual request can be made only by an organ procurement representative. This process is an important safeguard in distinguishing the act of treatment refusal from organ procurement. Because these potential donors may not always die after the discontinuation of life support, palliative care interventions must be available to respond to patient distress. It is unethical, before the declaration of death, to use any treatments or interventions aimed at preserving organs or assessing their suitability for dona-

tion that may harm the still-living patient by causing pain, causing traumatic injury, or shortening the patient's life. As long as the prospective donor is alive, the physician's primary duty is to the donor patient's welfare, not that of the prospective recipient.

THE ETHICS OF PRACTICE

The Changing Practice Environment

Many individuals, groups, and institutions play a role in and are affected by medical decisions. In an environment characterized by increasing demand for accountability and mounting health care costs, tension and conflicts are inevitable among patients, clinicians, insurers, purchasers, government, health care institutions, and health care industries. These sections of the Manual focus on the obligations of physicians in this context. However, it is essential to note that all parties are responsible for recognizing and supporting the importance of relationships with patients and the ethical obligations of clinicians to patients (86, 87). All parties must interact honestly, openly, and fairly (86). Furthermore, concern about the impact of the health care environment on physicians and insured patients should not distract physicians or society from attending to the unmet needs of persons who lack insurance or access to care. Questions of quality and access require public dialogue in which all parties should participate and require continued attention by physicians to their professional obligations to individual patients, and to the health care system. Resource allocation decisions should always be made through an open and participatory process.

Physicians have an obligation to promote their patients' welfare in a health care system that is increasingly complex. This entails forthrightly helping patients to understand clinical recommendations and make informed choices among all appropriate care options. It includes management of the conflicts of interest and competing commitments that arise in any practice environment. It also includes stewardship of finite health care resources so that as many health care needs as possible can be met, whether in the physician's office, in the hospital or long-term care facility, or at home.

The patient-physician relationship and the principles that govern it should be central to the delivery of care. These principles include beneficence, truth-telling, confidentiality, privacy, and advocacy when patient interests may be endangered by arbitrary, unjust, or inadequately individualized programs or procedures. Health care, however, does take place in a broader context beyond the patient-physician relationship. A patient's preferences or interests may conflict with the interests or values of the physician, an institution, a payer, or society.

The physician's first and primary duty is to the patient. Physicians must base their counsel on the interests of the individual patient, regardless of the physician's employment or practice status, the patient's insurance, or the medical care delivery setting. Whether financial incentives under fee-for-service prompt physicians to do more

Box 6. Ethics and population health.

Population health strives to integrate patient care and public health by improving care for individual patients, including the care experience, and adherence to appropriate quality metrics, improving health of populations, and reducing costs.

The physician's duty to the patient may at times be in tension with the aims of population health.

Physicians should support health systems that practice quality-driven and cost-effective medicine, but should not allow cost control and population-based goals to diminish commitment to and advocacy for individual patients.

rather than less, or capitation arrangements encourage them to do less rather than more, or pay-for-performance or other programs attempt to influence behavior, physicians must not allow such considerations to adversely affect their clinical judgment and the best interests of the individual patient (86).

The physician's duty to the patient may at times be in tension with the aims of population health (88), which strives to enhance the integration of patient care and public health (89) by improving care for individual patients including the care experience and adherence to appropriate quality metrics, improving health of populations, and reducing costs. Although physicians should support health systems that practice quality-driven and cost-effective medicine, they should not allow cost control and the "greater good" of populations to diminish their commitment to and advocacy for individual patients.

Population health ethics issues are noted in **Box 6**.

The physician's professional role is to make recommendations on the basis of the best available medical evidence and ethical standards, pursuing options that comport with the patient's unique health needs, values, and preferences (90).

Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly (91–93) in practicing high-value care. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient puts the patient first but also respects the need to use resources wisely and to help ensure that resources are equitably available. The goal of practicing parsimony, with its foundation in beneficence and non-maleficence, "is to provide the care necessary for the patient's good, not to reduce resource use (although it may in addition preserve resources)—a difference in intention that helps form the foundation for the ethical distinction between parsimonious medicine and rationing" (94). In making recommendations to patients, designing practice guidelines and formularies, making decisions on medical benefits review boards, or otherwise engaging in medical decision making, physicians' considered judgments should reflect the best available evidence in the biomedical literature, including data on the cost-effectiveness of different clinical approaches.

Patients should be informed of the rationale that underlies the physician's recommendation.

Guidance on stewardship of resources is noted in **Box 7**.

In instances of disagreement between patient and physician about tests or treatments, the physician is obligated to try to understand the patient's perspective, to explain the basis for the disagreement, to educate the patient, and to meet the patient's needs for comfort and reassurance. Providers of health insurance coverage are not obliged to underwrite approaches that patients may value but that are not justifiable on clinical or scientific grounds, or that are costly relative to comparably effective therapies for the same condition. However, there must be a fair appeals procedure.

The physician's duty further requires serving as the patient's agent, advocating through the necessary avenues to obtain treatment that is essential to the individual patient's care regardless of the barriers that may discourage the physician from doing so. Moreover, physicians should advocate just as vigorously for the needs of their most vulnerable and disadvantaged patients as for the needs of their most empowered patients (86).

Patients may not understand or may fear conflicts of interests for physicians and the competing commitments that can arise from cost-containment and other pressure from entities that finance health care. Physicians should disclose their potential conflicts of interest to their patients. While providers of health insurance coverage and institutions should hold physicians accountable for the quality, safety, and efficiency of care and not simply for economic performance, they also have duties to foster an ethical practice environment and should not ask physicians to participate in any arrangements that jeopardize professional and ethical standards or undermine the physician's role as patient advocate. Physicians should enter into agreements with insurers or others only if they can ensure that these agreements do not violate professional and ethical standards.

Accountable care organizations, pay-for-performance, and other programs can help improve the quality of care, but they must be aligned with the goals of medical professionalism. The main focus of the quality movement in health care should not, however, be on "pay for" or "performance" based on limited measures. Program incentives for a few specific elements of a single disease or condition may neglect the complexity of care for the whole patient, especially patients with multiple chronic conditions. Deselection of patients and "playing to the measures" rather than focusing on the patient are also dangers. Quality programs must put the needs and interests of the patient first (95).

Health systems, practices, and providers of health insurance coverage must disclose all relevant information, including as appropriate about benefits and any restrictions, and about financial incentives that might affect patient care or access to care. They should not restrict the information or counsel that physicians may give patients (86). When patients enroll in insurance

plans, they receive a great deal of information on rules governing benefits and reimbursement. Meaningful disclosure requires explanations that are clear and easily understood. Insured patients and their families bear a responsibility for having a basic understanding of the rules of their insurance (86). Physicians cannot and should not be expected to advise patients on the particulars of individual insurance contracts and arrangements. Patients should, however, expect their physicians to honor the rules of the insurer unless doing so would endanger the patient's health. Physicians should not collaborate with a patient or engage in efforts to deceive insurers or others.

Financial Arrangements

Financial relationships between patients and physicians vary. Financial arrangements and expectations should be clearly established, and fees and coding for physician services should accurately reflect the services provided. Physicians should be aware that a beneficent intention to forgive copayments for patients who are financially stressed may nonetheless be fraud under current law.

The practice of professional courtesy may raise ethical, practical, and legal issues. When physicians offer professional courtesy to a colleague, physician and patient should function without feelings of constraints on time or resources and care should be consistent with care provided to others. Colleague-patients who initiate questions in informal settings put the treating physician in a less-than-ideal position to provide optimal care; both parties should avoid this inappropriate practice.

As professionals dedicated to serving the sick, all physicians should provide services to uninsured and underinsured persons. Physicians who choose to deny care solely on the basis of inability to pay should be

aware that by thus limiting their patient populations, they risk compromising their professional obligation to care for the poor and the credibility of medicine's commitment to serving all classes of patients who are in need of medical care (96-98). Each individual physician is obliged to do his or her fair share to ensure that all ill persons receive appropriate treatment (18) and to honor the social contract with society (99).

Conflicts of Interest

The physician must seek to ensure that providing the medically appropriate level of care takes primacy over financial considerations imposed by the physician's own practice, investments, or financial arrangements. Trust in the profession is undermined when there is even the appearance of impropriety.

Potential influences on clinical judgment cover a wide range and include financial incentives inherent in the practice environment (such as incentives to overutilize in the fee-for-service setting or underutilize under capitation arrangements or rewards for physician implementation of institutional or other quality or population measures) (100, 101); drug, device, and other health care company gifts; and business arrangements involving referrals. Physicians must be conscious of all potential influences, and their actions should be guided by patient best interests and by principles of appropriate utilization, not by other factors.

Physicians who have potential financial conflicts of interest, whether as researchers, speakers, consultants, investors, partners, employers, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects (102). Physicians must disclose their financial interests to patients or research subjects, including interests in any medical facilities or office-based research to which they refer or recruit patients. When speaking,

Box 7. Patients first, and stewardship of resources.

The physician's first and primary duty is to the patient.

Physicians must base their counsel on the interests of the individual patient, regardless of the insurance or health care setting.

The physician's professional role is to make recommendations on the basis of the best available medical evidence and ethical standards, pursuing options that comport with the patient's unique health needs, values, and preferences.

Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly in practicing high-value care.

Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient puts the patient first but also respects the need to use resources wisely and to help ensure that resources are equitably available. Practicing parsimony has its foundation in beneficence and nonmaleficence, and its goal is to provide the care necessary for the patient's good, not resource reduction (although this may be a welcome secondary effect). This difference in intention helps define the ethical distinction between parsimonious medicine and rationing.

In making recommendations to patients, designing practice guidelines and formularies, making decisions on medical benefits review boards, or otherwise engaging in medical decision making, physician judgments should reflect the best available evidence, including on cost-effectiveness of different clinical approaches. Patients should be informed of the rationale that underlies the physician's recommendation.

Box 8. Physician–industry relations and gifts.

The acceptance by a physician of gifts, hospitality, trips, and subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged.

Even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest.

Physicians must gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment. Ask:

- What would the public or my patients think of this arrangement?
- What is the purpose of the industry offer?
- What would my colleagues think about this arrangement?
- What would I think if my own physician accepted this offer?

In all instances, it is the individual responsibility of each physician to assess any potential relationship with industry to assure that it enhances patient care.

Many industry payments and transfers of value to physicians must be reported under the federal Open Payments Program and laws in some states.

teaching, and authoring, physicians should disclose their interests in writing. Medical journal editors should be free from conflicts of interest.

Physicians should not refer patients to an outside facility in which they have invested and at which they do not directly provide care (103). Physicians may, however, invest in or own health care facilities when alternative capital funding is not available and necessary services are provided that would otherwise not be available. In such situations, in addition to disclosing these interests to patients, physicians must establish safeguards against abuse, impropriety, or the appearance of impropriety.

A fee paid to or by a physician for the referral of a patient, historically known as “fee-splitting,” is unethical. It is also unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells medical products or medications.

The sale of products from the physician's office might also be considered a form of self-referral and might negatively affect the trust necessary to sustain the patient–physician relationship. Most products should not be sold in the office unless the products are specifically relevant to the patient's care, offer a clear benefit based on adequate clinical evidence, and meet an urgent need of the patient (104). If geographic or time constraints make it difficult or impractical for patients to obtain a medically relevant and urgently needed product otherwise, selling a product in the office would be ethically acceptable. For example, a splint or crutches would be acceptable products, but vitamin supplements and cosmetic items are neither emergent treatments nor unlikely to be available elsewhere, and thus the sale of such products is ethically suspect. Physicians should fully disclose their financial interests in selling ethically acceptable products and inform patients about alternatives for purchasing the product. Charges for products sold through the office should be limited to the reasonable costs incurred in making them available. The selling of products intended to be free samples is unethical.

Physicians may invest in publicly traded securities. However, care must be taken to avoid investment decisions that may create a conflict of interest or the perception of a conflict of interest.

The acceptance by a physician of gifts, hospitality, trips, or subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged. Even small gifts can affect clinical judgment (105) and heighten the perception and/or reality of a conflict of interest. Physicians must gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment. In making such evaluations, physicians should consider the following: 1) What would the public or my patients think of this arrangement? 2) What is the purpose of the industry offer? 3) What would my colleagues think about this arrangement? and 4) What would I think if my own physician accepted this offer? In all instances, it is the individual responsibility of each physician to assess any potential relationship with industry to assure that it enhances patient care (102, 106). Many industry payments and transfers of value to physicians must be reported under the federal Open Payments Program (107) and laws in some states.

Guidance on physician–industry relations is noted in **Box 8**.

Physicians must critically evaluate all medical information, including that provided by detail persons, advertisements, or industry-sponsored educational programs. While providers of public and private graduate and continuing medical education may accept industry support for educational programs, they should develop and enforce strict policies maintaining complete control of program planning, content, and delivery. They should be aware of, and vigilant against, potential bias and conflicts of interest (108).

If medical professional societies accept industry support or other external funding, they also “should be

aware of potential bias and conflicts of interest and should develop and enforce explicit policies that preserve the independent judgment and professionalism of their members and maintain the ethical standards and credibility of the society" (108). At a minimum, medical societies should adhere to the Council of Medical Specialty Societies Code for Interactions with Companies (109).

Advertising

Advertising by physicians or health care institutions is unethical when it contains statements that are unsubstantiated, false, deceptive, or misleading, including statements that mislead by omitting necessary information.

THE PHYSICIAN AND SOCIETY

Society has conferred professional prerogatives on physicians with the expectation that physicians will use their position for the benefit of patients. In turn, physicians are responsible and accountable to society for their professional actions. Society grants physicians the rights, privileges, and duties pertinent to the patient-physician relationship and, therefore has the right to require that physicians be competent, knowledgeable, and respectful of the patient as a person.

Obligations of the Physician to Society

Physicians have obligations to society that parallel their obligations to individual patients. Physicians' conduct as professionals and as individuals should merit the respect of the community.

Physicians must fulfill the profession's collective responsibility to advocate for the health, human rights, and well-being of the public. Physicians should protect public health by reporting disease, injury, domestic violence, abuse, or neglect to the responsible authority as required by law.

Physicians should support initiatives that provide the public with accurate information about health care (for example, community education efforts) and should contribute to keeping the public properly informed by commenting on medical subjects in their areas of expertise. Physicians should provide news media with accurate information, recognizing this as an obligation to society, but confidentiality of patients must be respected.

Physicians should help the community and policymakers recognize and address the causes and social and environmental determinants of health, disease, and disability, including human rights concerns, discrimination, poverty, and violence. They should work toward ensuring access to health care for all persons; act to eliminate discrimination in health care; and help correct deficiencies in the availability, accessibility, and quality of health services, including mental health services, in the community. The denial of appropriate care to a class of patients for any reason is unethical. Importantly, disparities in care as a result of personal characteristics such as race and gender must be addressed (110). Physicians should also explore how their own

knowledge, beliefs, and attitudes influence their ability to fulfill these obligations.

Health and human rights are interrelated (111). When human rights are promoted, health is promoted. Violation of human rights has harmful consequences for the individual and the community. Physicians have important roles in promoting health and human rights and addressing social inequities, including caring for vulnerable populations, such as the uninsured and victims of violence. Indeed, the physician may be the only advocate for a vulnerable patient or community with pressing health care needs. Physicians have opportunities and duties to advocate for the health care needs of individual patients and also society.

Physicians should participate in patient safety initiatives, including error, sentinel event, and "near-miss" reporting. Human errors in health care are common (112), and many result from systems problems. Physicians should initiate process improvement and work with their institutions and in all aspects of their practices in an ongoing effort to reduce errors and improve care.

Resource Allocation

Medical care is delivered within social and institutional systems that must take overall health care resources into account. Increasingly, decisions about resource allocations challenge the physician's primary role as patient advocate. This advocacy role has always had limits. For example, a physician should not lie to third-party payers for a patient in order to ensure coverage or maximize reimbursement. Moreover, a physician is not obligated to provide all diagnostic tests and treatments without considering their effectiveness (113) (see also The Changing Practice Environment section in the Ethics of Practice). The just allocation of resources and changing reimbursement approaches present the physician with ethical quandaries. Nonetheless, there is wide agreement regarding two principles:

1. As a physician performs his or her primary role as a patient's trusted advocate, he or she has a responsibility to use all health care-related resources in an appropriate and efficient manner. He or she should plan work-ups carefully and avoid unnecessary testing, medications, surgery, and consultations.
2. Resource allocation decisions should be made at the policy level rather than in the context of an individual patient-physician encounter (that is, "at the bedside"). Ethical policy regarding allocation of health care resources is achieved best when all stakeholders consider and deliberate about the resources that exist, to what extent they are limited, costs, and how to balance these factors for equitable distribution.

Stakeholders, including physicians, other health care professionals, patients, patient advocates, insurers, and payers, should participate together in decisions at the policy level; should emphasize the value of health to society; should promote justice and fairness in health care; and should base allocations on medical

need, efficacy, cost-effectiveness, and proper distribution of benefits and burdens in society.

Relation of the Physician to Government

Physicians must not be a party to and must speak out against torture or other abuses of human rights. Participation by physicians in the execution of prisoners except to certify death is unethical. Under no circumstances is it ethical for a physician to be used as an instrument of government or others to weaken the physical or mental resistance of a human being, nor should a physician participate in or tolerate cruel or unusual punishment or disciplinary activities beyond those permitted by the United Nations' Standard Minimum Rules for the Treatment of Prisoners (114). Physicians must not conduct, participate in, monitor, or be present at interrogations (defined as a systematic effort to procure information useful to the purposes of the interrogator by direct questioning of a person under the control of the questioner; it is distinct from questioning to assess the medical condition or mental status of an individual) or participate in developing or evaluating interrogation strategies or techniques. A physician who becomes aware of abusive or coercive practices has a duty to report those practices to the appropriate authorities and advocate for necessary medical care. Exploiting, sharing, or using medical information from any source for interrogation purposes is unethical.

Limited access to health care is one of the most important characteristics of correctional systems in the United States (115). Physicians who care for prisoners may find it difficult to balance the best interests of the patient with those of the correctional system. Despite these challenges, physicians should make independent medical judgments and recommendations about what constitutes appropriate care for individual inmates consistent with standards of care, advocating for timely diagnostic assessments and treatment.

Cultural Humility and Volunteerism

Physicians should provide culturally sensitive care. Efficacy in this domain is enhanced by cultural humility, which emphasizes physician self-awareness, reflection, and a relationship-centered approach to each patient (116). With the goal of public service to underserved populations, physicians are increasingly participating in volunteer short-term experiences in global health (117). Successful volunteerism requires clear recognition of the individual's role as visitor, educator, and healer or trainee. Needs and objectives should be mutually understood without biases and prejudices. Medically trained interpreters should be utilized as appropriate to optimize communication and avoid missing important problems. The volunteer physician should be sensitive to local mores, customs, and issues of affordability.

Continuity and sustainability should guide the volunteer physician in working with the community, local physicians, and the health system to understand the health needs of the community and help prioritize them in cultural and economic context to achieve a lasting benefit, with an understanding of short- and long-term

impact. The outcomes should be desired by and the interventions acceptable to the affected population.

Discrimination violates the principles of professionalism and of the College. Volunteer physicians should encourage professionalism, promote education, and support public health initiatives.

Ethics Committees and Consultants

Ethics consultants and committees can respectfully facilitate resolution of conflicts in care through fair and inclusive decision-making processes by helping institutions shape policies and procedures that conform with ethical standards, and by assisting stakeholders in addressing current and future ethical problems by providing ethics education (118).

Accrediting organizations require health care organizations to have policies and procedures for handling ethical dilemmas that arise in clinical practice, such as through ethics consultation at the request of patients, nurses, physicians, or others (119). Physicians should be aware of organizational policies and procedures. Ethics consultation should be guided by standards, such as those developed by the American Society for Bioethics and Humanities (120). Ethics committees should be multidisciplinary and ensure that diverse perspectives are represented in order to address the complex problems and dilemmas with which they are confronted.

Medicine and the Law

Illness does not diminish the right or expectation to be treated equally, change a patient's legal rights, or permit a physician to ignore those legal rights.

The law is society's mechanism for establishing boundaries for conduct. Society expects those boundaries will not be disregarded. In instances of conflict, the physician must decide whether to violate the law for the sake of what he or she considers the dictates of medical ethics. Such a violation may jeopardize the physician's legal position or the legal rights of the patient. It should be remembered that ethical concepts are not always fully reflected in or adopted by the law. Violation of the law for purposes of complying with one's ethical standards may have consequences for the physician and should be undertaken only after thorough consideration and, generally, after consultation with colleagues or obtaining legal counsel.

Expert Witnesses

Physicians have specialized knowledge and expertise that may be helpful and needed in judicial or administrative processes. Often, expert testimony is necessary for a court or an administrative agency to understand the patient's condition, treatment, and prognosis. Physicians may be reluctant to become involved in legal proceedings because the process is unfamiliar and time-consuming. Their absence may result, however, in legal decisions that are made without the benefit of all relevant medical opinions and facts. Without the participation of physicians, dispute resolution may be unsuccessful, patients may suffer, and the public at large may be adversely affected.

Although physicians cannot be compelled to participate as expert witnesses, the profession as a whole has the ethical duty to assist patients and society in resolving disputes. In this role, physicians must have the expertise in the subject matter of the case and honestly and objectively interpret and represent the medical facts. The College lists specific qualifications for serving as an expert witness (121, 122). Physicians should accept only noncontingent compensation for reasonable time and expenses incurred as expert witnesses.

Strikes and Other Joint Actions by Physicians

Changes in the practice environment sometimes adversely affect the ability of physicians to provide patients with high-quality care and may challenge the physician's exercise of independent clinical judgment and even the ability to sustain a practice. However, physician efforts to advocate for system change should not include participation in joint actions that adversely affect patient access to health care or that result in anti-competitive behavior (123, 124). Physicians should not engage in strikes, work stoppages, slowdowns, boycotts, or other organized actions that are designed, implicitly or explicitly, to limit or deny services to patients that would otherwise be available. Individually and collectively, physicians should find advocacy alternatives, such as lobbying lawmakers and working to educate the public, patient groups, and policymakers about their concerns. Protests and marches that constitute protected free speech and political activity can be a legitimate means to seek redress, provided that they do not involve actions that may harm patients.

THE PHYSICIAN'S RELATIONSHIP TO OTHER CLINICIANS

Physicians share their commitment to care for all persons with an interdisciplinary team of health professionals. The team's ability to care effectively for the patient depends on the ability of the individuals on the team to treat each other with integrity, honesty, and respect in daily professional interactions regardless of race, religion, ethnicity, nationality, sex, gender identity, sexual orientation, age, or disability. Particular attention is warranted with regard to certain types of relationships and power imbalances, such as those between attending physician and resident, senior resident and intern, resident and medical student, or physician and nurse, and the potential for abusive or disruptive behavior or harassment (125-128).

Attending Physicians and Physicians-in-Training

The very title "doctor"—from the Latin *docere*, "to teach"—means that physicians have a responsibility to share knowledge and information with colleagues and patients. This sharing includes teaching clinical skills and reporting results of scientific research to colleagues, medical students, resident physicians, and other health care professionals.

The duty to teach is reviewed in **Box 9**.

Box 9. The duty to teach.

Doctor: from the Latin *docere*, "to teach."
Physicians have a responsibility to share knowledge and information with colleagues and patients.

Physicians and the medical profession have a responsibility to teach the science, art, and ethics of medicine to medical students, resident physicians, and others and to supervise physicians-in-training. Schools and institutions, regardless of their tax status, should facilitate teaching and foster an ethical environment for learners, in accord with ethical standards and accreditation requirements. Attending physicians must treat trainees and colleagues with respect, empathy, and compassion. In the teaching environment, graduated authority for patient management can be delegated to residents, with adequate supervision. All trainees should inform patients of their training status and role in the medical team. Trainees should inform the patient of their level of experience with any procedures that they are performing on the patient. Attending physicians, chiefs of service, or consultants should encourage residents to acknowledge their limitations and ask for help or supervision when concerns arise about patient care or the ability of others to perform their duties. The training environment should establish a culture of inquiry and scholarship and encourage trainees to raise ethical issues they may encounter and discuss sources of moral distress (129). Training programs should observe the requirements of regulatory bodies to avoid or reduce resident fatigue, optimize handovers or sign-outs, and help ensure patient safety and improve outcomes of care. While some of these training requirements are more recent (130), the obligation to serve the patient remains the same as in the past.

It is unethical to delegate authority for patient care to anyone, including another physician, who is not appropriately qualified and experienced. On a teaching service, the ultimate responsibility for patient welfare and quality of care remains with the patient's attending physician of record. When a patient declines to have trainees involved in her or his care, efforts should be made to discuss this with the patient, explaining the function and supervision of trainees and exploring alternative options when possible.

Prior permission from the patient's authorized representative to perform training procedures on the newly deceased patient should be obtained in light of any known preferences of the patient regarding the handling of her or his body or the performance of such procedures and applicable laws. Use of patient simulators for procedure training may obviate this practice.

Consultation and Shared Care

In almost all circumstances, patients should be encouraged to initially seek care from their principal physician. Physicians should in turn obtain competent consultation whenever they and their patients feel the need

for additional expertise (131). The purpose, nature, and expectations of the consultation should be clear to all.

The consultant should respect the relationship between the patient and the principal physician, should promptly and effectively communicate recommendations to the principal physician, and should obtain concurrence of the principal physician for major procedures or additional consultants. The consultant should also share his or her findings, diagnostic assessment, and recommendations with the patient, while taking the time to answer additional questions. The care of the patient should be transferred back to the principal physician with timely communication and documentation when the consultation is completed, unless another arrangement is agreed upon.

Consultants who need to take temporary charge of the patient's care should obtain the principal physician's cooperation and assent. The physician who does not agree with the consultant's recommendations is free to call in another consultant. The interests of the patient should remain paramount in this process.

A complex clinical situation may call for multiple consultations. To ensure a coordinated effort that is in the best interest of the patient, the principal physician should remain in charge of overall care, communicating with the patient and coordinating care on the basis of information derived from the consultations. Unless authority has been formally transferred elsewhere, the responsibility for the patient's care lies with the principal physician.

When a hospitalized patient is not receiving care from his or her principal physician, good communication between the treating physician and principal physician is key. The principal physician should supply the inpatient physician with adequate information about current and past clinical history to allow for appropriate decision making and care. The inpatient physician should keep the principal physician informed of the patient's clinical course and supply a timely and complete description of care. Changes in chronic medications and plans for follow-up care should be promptly communicated to the principal physician.

The patient-centered medical home model promotes whole-person, patient-centered, integrated care across the health care system (132) and has the overall responsibility for ensuring the coordination of care by all involved clinicians. Achieving these goals requires the collaboration and mutual respect of subspecialists, specialists, other clinicians, and health care institutions (133) in serving the patient.

The Impaired Physician

Physicians who are impaired for any reason must refrain from assuming patient responsibilities that they may not be able to discharge safely and effectively. Whenever there is doubt, they should seek assistance in caring for their patients.

Impairment may result from use of psychoactive agents (alcohol or other substances, including prescription medications) or illness. Impairment may also be caused by a medical or mental health condition, the

aging process (134), or profound fatigue that affects the cognitive or motor skills necessary to provide adequate care. The presence of these disorders or the fact that a physician is being treated for them does not necessarily imply impairment.

Every physician is responsible for protecting patients from an impaired physician and for assisting an impaired colleague. Fear of mistake, embarrassment, or possible litigation should not deter or delay identification of an impaired colleague (135). The identifying physician may find it helpful and prudent to seek counsel from a designated institutional or practice official, the departmental chair, or a senior member of the staff or the community.

Although the legal responsibility to do so varies among states, there is a clear ethical responsibility to report a physician about whom one has a reasonable concern regarding impaired medical judgment or practice to an appropriate authority (such as a chief of service, chief of staff, institutional or medical society assistance program, or state medical board). Physicians and health care institutions should assist impaired colleagues in identifying appropriate sources of help. While undergoing therapy, the impaired physician is entitled to full confidentiality as in any other patient-physician relationship. To protect patients of the impaired physician, someone other than the physician of the impaired physician must monitor the impaired physician's fitness to work. Serious conflicts may occur if the treating physician tries to fill both roles (136).

Peer Review

Professionalism entails membership in a self-correcting moral community. Professional peer review is critical in assuring fair assessment of physician performance for the benefit of patients. The trust that patients and the public invest in physicians requires disclosure to the appropriate authorities and to patients at risk for immediate harm.

All physicians have a duty to participate in peer review. Fears of retaliation, ostracism by colleagues, loss of referrals, or inconvenience are not adequate reasons for refusing to participate in peer review. Society looks to physicians to establish and enforce professional standards of practice, and this obligation can be met only when all physicians participate in the process. Federal law and most states provide legal protection for physicians who participate in peer review in good faith.

It is unethical for a physician to disparage the professional competence, knowledge, qualifications, or services of another physician to a patient or a third party or to state or imply that a patient has been poorly managed or mistreated by a colleague without substantial evidence. This does not mean that a physician cannot disagree with a plan of management or recommendations made by another physician. A physician therefore has a duty to patients, the public, and the profession to report to the appropriate authority any well-formed suspicions of fraud, professional misconduct, incompetence, or abandonment of patients by another physician.

In the absence of substantial evidence of professional misconduct, negligence, or incompetence, it is unethical to use the peer-review process to exclude another physician from practice, to restrict clinical privileges, or to otherwise harm the physician's practice.

Conflicts Among Members of a Health Care Team

All health professionals share a commitment to work together to serve the patient's interests. The best patient care is often a team effort; mutual respect, cooperation, and communication should govern this effort. Each member of the patient care team has equal moral status. When a health professional has important ethical objections to an attending physician's order, both should discuss the matter openly and thoroughly. Mechanisms should be available in hospitals and outpatient settings to resolve differences of opinion among members of the patient care team. Ethics committees or ethics consultants may also be appropriate resources.

RESEARCH

Medical progress and improved patient care depend on innovative and rigorous research, on honest communication of research results, and on continued evaluation of patient outcomes following implementation of research findings. Research is defined under the federal "Common Rule" as "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (137). Honesty and integrity must govern all types and stages of research, from the laboratory to randomized clinical trials, and from the initial design and grant application to publication of results and translation into practice. Institutional review boards (IRBs) must review and approve research involving human subjects to ensure consistency with ethical and regulatory standards, but IRB review does not obviate the investigator's responsibilities to uphold the ethical integrity of research. Investigators and their institutions, authors, and journal editors are individually and jointly responsible for ensuring that the obligations of honesty and integrity are met. Research misconduct, which includes fraud, fabrication, falsification, and plagiarism of research, must be condemned and punished. Reviewers of grant applications and journal articles must respect the confidentiality of new ideas and information; they must not use what they learn from the review process for their own purposes, and they should not misrepresent the ideas of others as their own.

Scientists have a responsibility to gather data meticulously, to keep impeccable records with appropriate levels of privacy protections, to interpret results objectively and not force them into preconceived molds or models, to submit their work for peer review, and to report knowledge. All clinical trials must be registered (for example, with ClinicalTrials.gov), and reporting of methodology and outcomes must be clear, complete, and transparent (138). Data should be available for sharing (139).

Contributing to generalizable knowledge that can improve human health should be the main motivation for scientific research. Personal recognition, public acclaim, or financial gain should not be primary motivating factors, and physicians should be aware of conflicting interests when participating in or referring patients to research studies.

Protection of Human Subjects

The medical profession and individual researchers must assume responsibility for assuring that research is valid, has potentially important value, and is ethically conducted. Research must be thoughtfully planned to ensure a high probability of valid results, to minimize subject risk and maximize subject safety, and to achieve a benefit-risk ratio that is high enough to justify the research effort (140). Benefits and risks of research must be distributed fairly, and particular care must be taken to avoid exploitation of vulnerable populations and those in countries with limited access to health care resources (141). Research projects originating in but conducted outside of the United States must be consistent with ethical principles and practices that govern human subjects research and must adhere to regulatory standards in the United States as well as at international sites.

Functioning as both an investigator and the clinician of a patient-subject can result in conflict between what is best for the research protocol and what is in the patient's best interests. Physician-investigators should disclose this conflict to potential research participants and should maintain patient-subject health and welfare as their primary consideration (142). Patients should be informed that the primary objective of a research protocol is to gain knowledge and that there may or may not be clinical benefit. It should also be clear to patients that participation in research is voluntary and not a requirement for continued clinical care. The right to withdraw consent and discontinue participation at any time must be communicated. Any limitations on withdrawal of data or biological materials must be explained during the consent process.

Each research subject or an authorized representative must be fully informed of the nature and risks of the research so that he or she may give informed consent to participate. Physicians have an ethical obligation to ensure that the information shared during the informed consent process is appropriate and understandable to the proposed subject population. Agreement to participate in research should never be coerced, but undertaken freely by a subject (or authorized by a legally appointed representative) who is adequately informed to make the decision. Some groups may be more vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons, as included in the Common Rule [137]). Special efforts must be undertaken to protect such populations and individuals.

Temporary, progressive, or permanent cognitive impairment or a questionable capacity to give consent

for participation in research does not preclude participation in research, but does necessitate special measures (143). Research involving individuals with impaired cognition or capacity still needs to meet threshold criteria of a high probability of valid results, a benefit-risk ratio that is high enough to justify the research effort, and a fair distribution of research benefits and risks. Institutions and physician-investigators should attempt to obtain the assent of the cognitively impaired individual in addition to obtaining the consent of a legally authorized representative. A patient may be able to give consent for research participation and designate a proxy in the early stages of disease. If there is no advance directive or proxy, the legally appointed surrogate decision maker must first consider whether the patient would have agreed to participate. The physician-investigator must reinforce that surrogate decision-making standards are based on the patient's best interests. If a subject regains decision-making capacity, he or she should be given the opportunity to engage in the consent process (144). Clinicians who are thinking about participating in or referring patients to research studies should be well versed about the responsible conduct of research and protection of human subjects.

Research involving special circumstances, such as individuals requiring critical care or emergency care, also requires special measures for the protection of human subjects. Although research in these contexts may contribute to improved care, investigators need to be aware that the subject may have an impaired ability to provide informed consent and that the benefits of this research may not flow to the potential subject. Special precautions should be undertaken to ensure the protection of these subjects (145, 146). However, the extent to which some precautions, such as community consultation, have been protective of subject and community rights and interests is unclear.

Independent review is a fundamental principle of ethical research. All proposed research, regardless of the source of support, must be assessed by an IRB to assure that the research plans are valid and reasonable, human subjects are adequately protected, the benefit-risk ratio is acceptable, the proposed research is sufficiently important and protective of human subjects in light of the local patient population, and the informed consent process and confidentiality protections are both appropriate and adequate. Physician-investigators and physicians referring patients to clinical studies have an independent, professional obligation to satisfy themselves that those studies meet ethical standards. When a single IRB reviews a multisite study, physicians should help ensure the local patient population and local context are considered in study design, review, and conduct (147, 148).

Human subjects research ethics requirements are reviewed in **Box 10**.

While the formal, independent review process was designed to protect research subjects, it cannot replace mutual trust and respect between subjects and researchers. Maintaining that trust and respect requires that physician-investigators involved in designing, per-

Box 10. Human subjects research.

All proposed research, regardless of the source of support, must be assessed by an institutional review board to assure that:
The research plans are valid and reasonable;
Human subjects are adequately protected;
The benefit-risk ratio is acceptable;
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The informed consent process and confidentiality protections are both appropriate and adequate.

Physician-investigators and physicians referring patients to clinical studies have an independent professional obligation to satisfy themselves that those studies meet ethical standards.

forming, or referring patients to research studies have primary concern for the potential subjects (149, 150). If the risks of continued participation in a research trial become too great or cannot be justified, the physician-investigator must advise patients to withdraw. Physicians should not abdicate overall responsibility for patients they have referred to research studies and should ensure that data and safety issues are routinely monitored.

Although the responsibility for assuring reasonable protection of human research subjects resides with the investigators and the IRB, the medical profession as a whole also has responsibilities. Clinical investigation is fraught with potential conflicts. Rewards should not be linked to research outcomes, and physicians participating in the conduct of clinical studies should avoid such situations. Moreover, physicians who enroll their own patients in office-based research have an ethical obligation to disclose whether they have financial or other ties to sponsors (102). Giving or accepting finder's fees for referring patients to a research study generates an unethical conflict of interest for physicians (102). Compensation for the actual time, effort, and expense involved in research or recruiting patients is acceptable; any compensation above that level represents a profit and constitutes or can be perceived as an unethical conflict of interest.

While the Common Rule (137) and some state laws have provisions regarding privacy and confidentiality requirements for research, the HIPAA Privacy Rule (23) requires subject authorization for use or disclosure of protected health information for research. A privacy board can waive the authorization requirement or information can be used in a "limited data set" with a data use agreement or can be deidentified under HIPAA (151), although the HIPAA deidentification requirements are stricter than those under the Common Rule. Physicians who engage in research studies or who make their patient records available for research purposes should be familiar with the privacy and data use requirements and each study's procedures for protecting data confidentiality and security.

Use of Human Biological Materials in Research

Research with human biological materials, including whole-genome sequencing research, has implications for the privacy of research subjects and individuals with a genetic relationship to research subjects. The potential for discrimination or other serious harm through the inappropriate or unauthorized disclosure of genetic data must be communicated during the informed consent process and steps taken to minimize this risk. Research subjects should be informed of plans to pool or otherwise share biological materials, including in biobanks or for the development of commercial products from these materials. In addition, research subjects should be informed that it may not be possible to withdraw deidentified or anonymized biological data from research use.

Fully informed and transparent consent requires the disclosure of all potential uses of patient data and biological materials. During the initial consent process, desired preferences of research subjects regarding sharing research results with biological relatives and consent for additional research participation should be requested. Research subjects should be given the option to receive incidental or secondary research findings that are actionable, and to be provided appropriate clinical follow-up or referral (152). Research should be limited to the use specified by the protocol during the informed consent process. Communication of the risks and benefits of research involving biological material allows research subjects to make a well-informed decision.

Placebo Controls

Physicians may be asked to enroll patients in placebo-controlled trials. Ideally, research should test new interventions “against those of the best current proven intervention” (153). Placebos may be used, however, when there is no proven intervention or when existing interventions offer no meaningful improvement to length or quality of life or are so intolerable that patients routinely refuse them (154). Placebos are also justifiable when not treating would be an acceptable medical option, or when compelling and scientifically sound methodological reasons require placebos to establish the safety and efficacy of an intervention (and patients receiving placebos or no treatment will not be subject to additional risk for serious harm) (153, 155).

Placebo-controlled studies require that the study design has been reviewed and approved by an independent IRB. Subjects must freely consent to suspend knowledge of whether they are receiving effective treatment.

Before referring patients to a placebo-controlled study, a physician should ensure that the study design provides for unblinding treatment assignment to the treating physician.

Innovative Medical Therapies and Research

The use of innovative medical therapies falls along the continuum between established practice and research. Innovative therapies include the use of uncon-

ventional dosages of standard medications, novel combinations of currently accepted practices, new applications of standard interventions, and the use of accepted therapies or approved drugs for nonapproved indications. The primary purpose of innovative medical therapies is to benefit the individual patient. While medical innovations can yield important treatment results, they can also produce safety problems. Consequently, medical innovation should always be approached carefully. When considering an innovative therapy that has no precedent, the physician should consult with peers, an IRB, or other expert group to assess the risks, potential adverse outcomes, and potential consequences of forgoing a standard therapy, and whether the innovation is in the patient’s best interest (156). Informed consent is particularly important and requires that the patient understand that the recommended therapy is not standard treatment. Adverse events should be carefully monitored and reported to the U.S. Food and Drug Administration (FDA) and applicable oversight bodies. If use of the new therapy, procedure, or intervention becomes routine, it should be investigated in a clinical trial (153). Innovative medical therapy should be treated as research whenever data are gathered to develop new medical information and for publication.

FDA-approved expanded access programs for drugs and medical products (157) assess risk versus benefit, provide protections, and maintain necessary oversight in the interest of patients and the public health. Making unapproved products and drugs available to patients with life-threatening illnesses without FDA oversight, as through right-to-try laws, can harm patients, the integrity of science, and the regulatory role and mission of the FDA.

Internet and Social Media Research

Social media and social networking sites may create unique ethical challenges (15). When research is conducted using online technologies, issues of informed consent and privacy remain paramount. Physicians who enroll patients in social media research or refer them to such studies must be aware of how to recruit appropriately via social media and how to ensure truly informed consent and privacy in the digital setting (158).

Scientific Publication

Authors of research reports must be intimately acquainted with the work being reported so that they can take public responsibility for the integrity of the study and the validity of the findings. Authorship means substantial contribution to the research along with compliance with authorship guidelines (159). They must also have substantially contributed to the research itself, and they must have been part of the decision to publish. Investigators must disclose project funding sources to potential research collaborators and publishers and must explicitly inform publishers whether they do or do not have a potential conflict of interest (see the Conflicts of Interest section). Physicians should not participate in research if the publication of negative results will be precluded.

Physician-investigators build on the published work of others and can proceed with confidence only if they can rely on the accuracy of the previously reported results on which their work is based. Registration of clinical trials in a public trials registry before patient enrollment helps address the general public's and scientific community's call for transparency in clinical research (160). All researchers have a professional responsibility to be honest in their publications. Biased reporting and selective reporting of study outcomes risk the integrity of the research and may interfere with the ability to derive evidence-based treatment outcomes (161). Researchers must describe methods accurately and in sufficient detail and assure readers that the research was carried out in accordance with ethical principles. They have an obligation to fully report observations actually made, clearly and accurately credit information drawn from the work of others, and assign authorship only to those who merit and accept it. Equally important is disclosing the financial associations of authors and other potential conflicts of contributors in the manuscript (162).

In general, subject recruitment alone does not merit authorship (163). Ghostwriting or taking credit or payment for the authorship of another is unethical (102).

Plagiarism is unethical. Incorporating the ideas of others or one's own published ideas, either verbatim or by paraphrasing, without appropriate attribution, is unethical and may have legal consequences.

Sponsored Research

All scientists are bound by the obligations of honesty and integrity in their research. However, in the high-stakes arena of the health care industry, industry-sponsored research is at greater risk for conflicts of interest. Scientists have a responsibility to protect human subjects, implement applicable research standards and privacy and confidentiality protections, register trials, interpret results objectively, submit their work for peer review, and disclose all conflicts of interest. With industry-sponsored research, scientists have the further obligations of ensuring that the entire data set is available and analyzed independently of the sponsor (164).

Public Announcement of Research Discoveries

In this era of rapid communication and intense media and public interest in medical news, clinical investigators or their institutions commonly make public announcements of new research developments. Because media coverage of scientific developments can be fraught with misinterpretation, unjustified extrapolation, and unwarranted conclusions (165), researchers should approach public pronouncements with extreme caution, using precise and measured language. Caution is especially important when reporting findings via social media, where content may be exceptionally brief and shared rapidly. Researchers should also consider notifying subjects of study findings.

In general, press or media releases should be issued and press conferences held only after the research has been published or presented in proper and

complete abstract form so that study details are available to the scientific community for evaluation. Statements of scientists receive great visibility. An announcement of preliminary results, even couched in the most careful terms, is frequently reported by the media as a "breakthrough." Scientists and spokespersons must work together to avoid raising false public expectations or providing misleading information, both of which reduce the credibility of the scientific community as a whole.

CONCLUSION

Medicine poses challenging ethical dilemmas for patients, clinicians, and institutions. We hope that this Manual will help physicians—whether they are clinicians, educators, or researchers—and others to address these issues. The Manual is written for physicians by a physician organization as we attempt to navigate through sometimes difficult terrain. Our ultimate intent is to enhance the quality of care provided to patients. We hope the Manual will help thoughtful readers to be virtuous physicians, trusted by patients and the public.

APPENDIX: A 6-STEP APPROACH TO ASSIST CLINICAL ETHICS DECISION MAKING

Step 1: Assess the Medical Situation

Get all of the facts "on the table" at the beginning to enable the various participants to gain a common understanding of the situation, even if they disagree about what to do next.

Example: For purposes of an example here, consider a case involving a patient with AIDS who is unconscious and on life support.

- What are the medical facts and any uncertainties (for example, prognosis; outcomes with and without treatment)? Are additional data needed to support decision making?
- What are the psychological and social factors that will affect decision making?

Step 2: Frame the Pending Medical Decision and Ethical Question

Ethical dilemmas often arise at a decision node. Define the pending options and whether each is feasible (which may itself be subject to debate).

Example: Should a ventilator be continued or not for an unconscious patient with AIDS who cannot speak for himself?

- What are the options? What is the feasibility of each option?
- What is the decision that needs to be made? Frame this as an "ought" or "should" question.

Step 3: Determine the Principles and Interests Involved in the Ethics Question

Answers to ethics questions should consider reasons for right action guided by ethical principles and interests.

Example: This case involves principles of beneficence, nonmaleficence, and respect for patient autonomy. Virtues of the physician, such as honesty, wisdom, patience, and compassion, are also relevant.

- What are the ethical principles at issue—beneficence (act in the best interests of the patient), nonmaleficence (do no harm), respect for patient autonomy, justice?
- Consider also using virtue ethics (an approach to ethics emphasizing the role of physician character and virtue rather than duties or consequence of actions) to help determine how a good physician might act in such a case.

Step 4: Who Are the Participants, and What Are Their Motivations?

Seek to understand the various and possibly conflicting motivations of involved individuals. Err on the side of inclusivity.

Example: The patient's partner and parents all say they speak for the patient. Should the patient's partner or parents be the surrogate decision maker for this patient?

- What did the patient want (for a patient with decision-making capacity, what does the patient want)? Who best knows the patient and his wishes for care?
- Who has a stake in the outcome?
- What are the needs, motivations, preferences, values, and obligations of each participant?
- What is the strength of each participant's claim, based on her/his relation to the patient?

Step 5: Balancing Principles and Interests to Reach Resolution

This step is the core of the ethics consultation and should provide reasoned arguments for action. Successful ethics consultation also aims to protect informed/shared decision making by building consensus.

Example: The patient's partner has been designated his health care agent in an advance directive with specific written instructions.

Which of the principles, interests, and motivations delineated in steps 3 and 4 are most compelling?

If consensus cannot be reached, whose claim for decision-making authority and which arguments are the strongest, based on ethical principles?

- What argument would you present to lead all those involved to agree with what you think is the best way forward?

Step 6: Preventive Ethics Review

Every ethics consult provides an opportunity to learn. Consider how this ethical dilemma might have been avoided.

- How might the situation be avoided the next time around?

- Are there modifiable structural aspects of the institution/ health care delivery system that contributed to the dilemma?
- Might a conversation about the situation among interested participants have prevented the ethical conflict?

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Acknowledgment: The College and the ACP Ethics, Professionalism and Human Rights Committee thank former Committee members who made contributions to the development of the Manual through their work on previous editions. They also thank the many leadership, journal, and other reviewers of this edition of the Manual for helpful comments on drafts; Matthew DeCamp, MD, PhD, for consulting and research assistance with the research chapter of the Manual, for which contributions he received compensation; and staff to the Committee from the ACP Center for Ethics and Professionalism, Daniel T. Kim, Lois Snyder Sulmasy, and Kathy Wynkoop, who worked on this edition.

Financial Support: Financial support for the development of the Manual came exclusively from the ACP operating budget.

Disclosures: Disclosure forms can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M18-2160.

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