

AHA/ACC CONSENSUS CONFERENCE REPORT

2020 American Heart Association and American College of Cardiology Consensus Conference on Professionalism and Ethics

A Consensus Conference Report

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Key Words: clinical coding ■ conflict of interest ■ cultural diversity ■ delivery of health care ■ documentation ■ electronic health records ■ ethics ■ health equity ■ personal autonomy ■ privacy ■ professionalism ■ racism ■ social justice

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1. INTRODUCTION

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The 2020 American Heart Association and American College of Cardiology Consensus Conference on Professionalism and Ethics (2020 Consensus Conference) comes at a time even more fraught than the eras of the 3 previous meetings on the same topics. A virulent pathogen has challenged the physical and economic health of the entire country; a series of tragedies have awakened a sense of social justice previously unexpressed nationally; and the political climate rivals the divisiveness seen at the birth of the nation.¹ Arguably, there could be no better time to review and take a fresh perspective on medical ethics and professionalism in the light of established norms and current stressors. In addition, the American Heart Association (AHA) and the American College of Cardiology (ACC) recognize that this important assessment should be undertaken on a more regular basis. There should be no more 16-year gaps.

Building on a solid understanding of previous similar efforts and with a firm appreciation of the obligations of medicine's social contract, the tenets of medical ethics, and the principles and commitments of medical professionalism, the ACC and the AHA sponsored a conference on medical professionalism and ethics on October 19 to 20, 2020. Multiple medical professional organizations provided valuable input. The purpose of the present 2020 Consensus Conference is to address the practical management of professional and ethical behavior of cardiovascular clinicians and scientists and to make specific recommendations in light of contemporary issues of professionalism and ethics. The consensus committee reviewed previously published documents and current materials to formulate their recommendations.

1.1. Historical Perspective and Current Plan

The AHA and the ACC have long individual and collective histories of formally addressing issues of medical ethics and medical professionalism. The 21st Bethesda Conference (Ethics in Cardiovascular Medicine) was held in October 1989²; the 29th Bethesda Conference (Ethics in Cardiovascular Medicine [1997]) was held in October 1997³; and the collaborative effort (ACC/AHA Consensus Conference on Professionalism and Ethics) was held in June 2004.⁴ The specific major topics and subtopics discussed in these conferences reflect the ethical and professional issues extant at the time of the assemblies.

The 21st Bethesda Conference² was devoted to discussions of ethical decision making in medicine; the relation of cardiovascular specialists to patients, other physicians, and physician-owned organizations; the allocation of limited resources in cardiovascular medicine; scientific responsibility and integrity in medical research; and the relation of cardiovascular specialists to industry, institutions, and organizations.

Subtopics included in the 21st Bethesda Conference discussion were the following: acting in the patient's interest; respecting the patient's preferences; distributive justice; physician responsibilities to society; medical decision making; end-of-life decisions; AIDS and the cardiovascular physician; conflicts of interest (COIs) and ethics in medical education; resource limitations and distribution; end-of-life care; cost and efficacy of medical technology; the welfare of the individual patient and the welfare of society; responsibilities of clinical investigators, research objectivity, credibility, and COIs; specific physician relationships with industry (RWIs); physician ownership of healthcare facilities; and physicians' relationships to institutions and organizations.

The 29th Bethesda Conference³ discussed external influences on the practice of cardiology, application of medical and surgical intervention near the end of life,

and clinical research in a molecular era and the need to expand its ethical imperatives.

Subtopics discussed in the 29th Bethesda Conference included managed care and the reinterpretations of ethical standards and the concept of professionalism; the relationship of medical ethics and business ethics; the application of medical and surgical interventions in elderly patients; palliative care; futile care; forgoing treatment and advance care planning; physician-assisted suicide; ethical considerations in the conduct of clinical trials; the ethical, legal, and social implications of the Human Genome Project; data confidentiality; and genetic information and its implications for medical insurance.

The ACC/AHA Consensus Conference⁴ dwelt on codes of conduct in human subjects research (HSR); investigator participation in clinical research; disclosure of relationships with commercial interests and policies for educational activities and publications; appropriate clinical care and issues of self-referral; expert testimony and opinions; and a code of conduct for organizational staff and volunteer leadership.

Subtopics treated in the ACC/AHA Consensus Conference were COIs and proper disclosure; formal scrutiny of research involving human subjects; confidentiality in research activities; indemnification of research activities; avoidance of bias in clinical trials; physician self-referral; direct-to-consumer advertising; cardiovascular specialty hospitals and physician financial COIs; antikickback statutes; Stark laws; expert testimony in professional liability, class action litigation, and patent issues; and nonprofit organizational governance, management, and potential COIs.

For the 3 prior ACC or ACC/AHA ethics and professionalism conferences, there were 164 unique attendees; 11.6% were identified as women, and 2.4% were identified as Black. Twenty of the 164 attendees were present at 2 or 3 of the conferences. Of the 164 attendees, 20 were past, present, or future ACC presidents, and 13 were past, present, or future AHA presidents. No attendees were identified as early career or fellows-in-training.

In the 2020 Consensus Conference, of the 61 participating attendees, 41.2% were women, 7.9% were Black, and 4.8% were Hispanic. Three of the 61 were present at the prior conference in 2004; 6 were past, present, or future ACC presidents; and 4 were past, present, or future AHA presidents. Two 2020 Consensus Conference attendees were identified as early career, and 4 were fellows-in-training. Figure 1 shows comparative attendee demographic data for the combined earlier conferences and for the 2020 Consensus Conference.

Figure 2 shows the academic degrees and professional representations of the attendees at the current conference and at each of the 3 previous conferences.

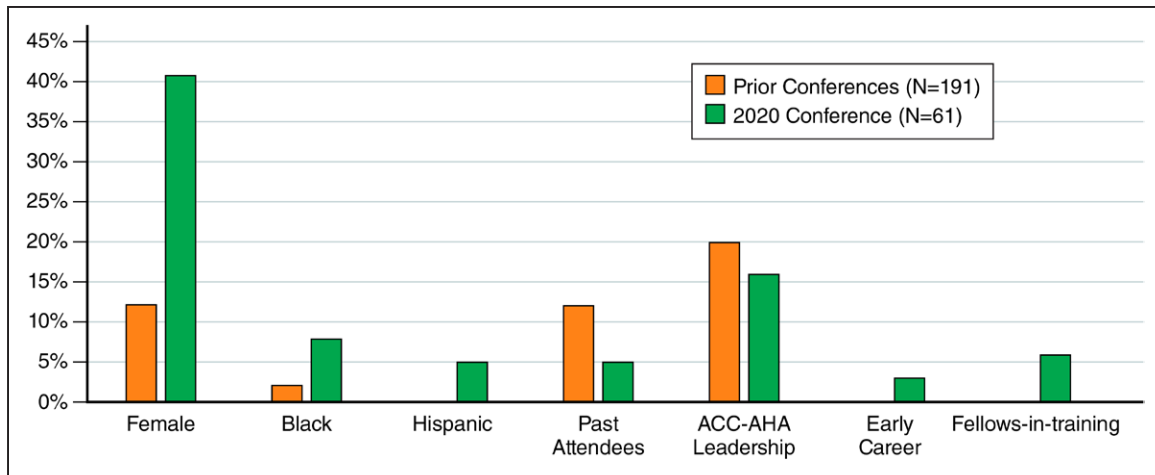


Figure 1. American Heart Association (AHA)/American College of Cardiology (ACC) conferences on professionalism and ethics: attendee demographics.

It is important to note that for the purpose of the current conference, the ascendancy of the team care paradigm in 21st century cardiovascular medicine is recognized, and references to physicians in prior publications, by extension, include all members of the healthcare team. In this document, the terms *clinician*, *practitioner*, and *medical professional* will be used in lieu of the term *provider*.

This document is a comprehensive summary of the deliberations of the 5 task forces that made up the 2020 Consensus Conference. Throughout the preparation of this report, efforts were made to be as concise as reasonably possible; however, because this is envisioned to be a reference document, essential detail was deliberately not euthanized for the sake of brevity.

1.2. Context Framing

These conferences have reinforced the notion that the operative underpinning for the practice of medicine in the United States is a set of principles of medical ethics. These principles also form the basis for medical professionalism and what has become known in more recent

years as medicine’s social contract. Ethical medical practice is an a priori assumption of medicine’s social contract, and the principles of ethics shape that contract, giving rise to the concept of professionalism and the rules by which that contract is implemented from the perspective of the medical professional.^{5,6}

The American College of Physicians⁷ and the American Medical Association (AMA)⁸ have codes of ethics for physicians. The American College of Physicians’ Ethics Manual provides context, for example, in reviewing the principles of medical ethics and reminding us that *Medicine is not, as Francis Peabody said, “a trade to be learned, but a profession to be entered.” 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. Physicians must individually and collectively fulfill the duties of the profession.*⁷

The tenets of medical ethics, the principles and commitments of medical professionalism, and the specific

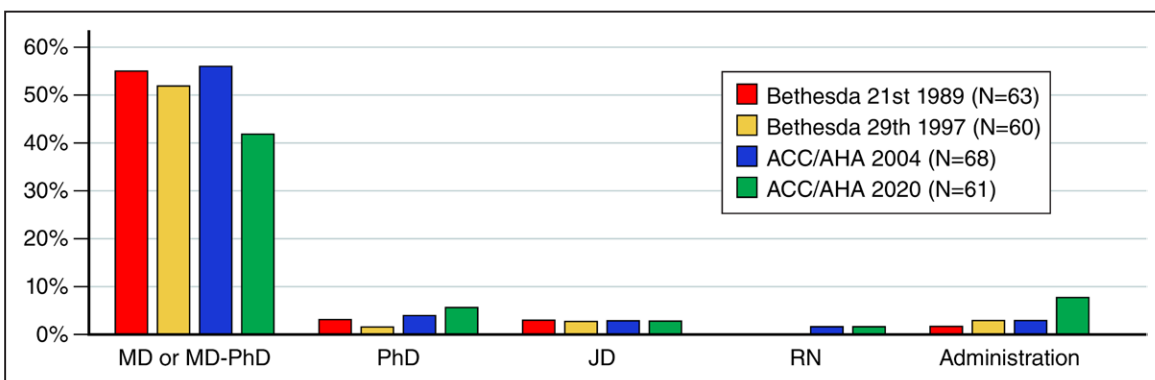


Figure 2. American Heart Association (AHA)/American College of Cardiology (ACC) Conferences on Professionalism and Ethics: attendee academic and professional representation.

Mean conference attendance=63.

obligations of medicine's social contract form the basis of this joint AHA/ACC study of medical ethics and professionalism in the 21st century. By way of creating a common ground of understanding, in this introduction, each of these 3 sets of elements is reviewed.

1.3. The Tenets of Medical Ethics

The classic ethical principles of medical practice are duties based in respect for autonomy, beneficence, non-maleficence, and justice.^{7,9}

- **Respect for autonomy.** The duty to protect and foster a patient's free, uncoerced choices.
- **Beneficence.** The duty to promote good and to act in the best interest of the patient.
- **Nonmaleficence.** The duty to do no harm in every interaction with patients.
- **Justice.** There should be fairness and equity in health care.

1.4. The Principles and Commitments of Medical Professionalism

The *Physician Charter on Medical Professionalism* was published in 2002 as a collaboration between the American Board of Internal Medicine Foundation, the American College of Physicians–American Society of Internal Medicine Foundation, and the European Federation of Internal Medicine.¹⁰ Both the ACC and the AHA have officially endorsed the charter, as have >100 other medical professional organizations across the world.¹¹ The charter contains eloquent, succinct, and actionable expressions of the principles and commitments of medical professionalism. Its descriptors are reproduced here with permission.¹⁰

1.4.1. Principles of Professionalism

- **Primacy of patient welfare.** This principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the physician-patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.
- **Patient autonomy.** Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care.
- **Social justice.** The medical profession must promote justice in the healthcare system, including the fair distribution of healthcare resources. Physicians should work actively to eliminate discrimination in health care, whether based on race,

sex, socioeconomic status, ethnicity, religion, or any other social category.

1.4.2. Commitments of Professionalism

- **Professional competence.** Physicians must be committed to lifelong learning and be responsible for maintaining the medical knowledge and clinical and team skills necessary for the provision of quality care. More broadly, the profession as a whole must strive to see that all of its members are competent and must ensure that appropriate mechanisms are available for physicians to accomplish this goal.
- **Honesty with patients.** Physicians must ensure that patients are completely and honestly informed before the patient has consented to treatment and after treatment has occurred. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on the course of therapy. Physicians should also acknowledge that in health care, medical errors that injure patients sometimes do occur. Whenever patients are injured as a consequence of medical care, patients should be informed promptly because failure to do so seriously compromises patient and societal trust. Reporting and analyzing medical mistakes provide the basis for appropriate prevention and improvement strategies and for appropriate compensation to injured parties.
- **Patient confidentiality.** Earning the trust and confidence of patients requires that appropriate confidentiality safeguards be applied to disclosure of patient information. This commitment extends to discussions with individuals acting on a patient's behalf when obtaining the patient's own consent is not feasible. Fulfilling the commitment to confidentiality is more pressing now than ever before, given the widespread use of electronic information systems for compiling patient data and an increasing availability of genetic information. Physicians recognize, however, that their commitment to patient confidentiality must occasionally yield to overriding considerations in the public interest (for example, when patients endanger others).
- **Maintaining appropriate relations with patients.** Given the inherent vulnerability and dependency of patients, certain relationships between physicians and patients must be avoided. In particular, physicians should never exploit patients for any sexual advantage, personal financial gain, or other private purpose.
- **Improving quality of care.** Physicians must be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also

working collaboratively with other professionals to reduce medical error, to increase patient safety, to minimize overuse of healthcare resources, and to optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and the application of quality measures to routinely assess the performance of all individuals, institutions, and systems responsible for healthcare delivery. Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

- **Improving access to care.** Medical professionalism demands that the objective of all healthcare systems be the availability of a uniform and adequate standard of care. Physicians must individually and collectively strive to reduce barriers to equitable health care. Within each system, the physician should work to eliminate barriers to access based on education, laws, finances, geography, and social discrimination. A commitment to equity entails the promotion of public health and preventive medicine, as well as public advocacy on the part of each physician, without concern for the self-interest of the physician or the profession.
- **A just distribution of limited finite resources.** While meeting the needs of individual patients, physicians are required to provide health care that is based on the wise and cost-effective management of limited resources. They should be committed to working with other physicians, hospitals, and payers to develop guidelines for cost-effective care.
- **Scientific knowledge.** Much of medicine's contract with society is based on the integrity and appropriate use of scientific knowledge and technology. Physicians have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence and physician experience.
- **Maintaining trust by managing COIs.** Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. Physicians have an obligation to recognize, to disclose to the general public, and to deal with COIs that arise in the course of their professional duties

and activities. Relationships between industry and opinion leaders should be disclosed, especially when the latter determine the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

- **Professional responsibilities.** As members of a profession, physicians are expected to work collaboratively to maximize patient care, to be respectful of one another, and to participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should also define and organize the educational and standard-setting process for current and future members. Physicians have both individual and collective obligations to participate in these processes. These obligations include engaging in internal assessment and accepting external scrutiny of all aspects of their professional performance.

1.5. The Obligations of Medicine's Social Contract

Medicine's social contract is an agreement between 2 parties: society as a whole and medical practitioners.^{12,13} Some elements of the contract are tacit, and some are codified in the laws and regulations governing the practice of medicine. Examples of the latter are laws establishing the healthcare system, educational requirements, and licensure. The tacit elements are behaviors and attitudes expressed by practitioners such as honesty, commitment, compassion, and altruism, none of which are concepts suitable for legislative or regulatory actions. Contracts—tacit or written—document the obligations agreed to by the parties involved. The obligations of the healthcare social contract, as delineated by Cruess and Cruess,¹⁴ are as follows:

1.5.1. Medical Practitioners Agree to:

- **Fulfill the role of the healer.** The healer is an elemental and well-defined role in all human societies. Attributes of the healer include caring and compassion; insight and self-awareness; openness; respect for the healing function; respect for patient dignity and autonomy; being fully present and without distraction for the patient; and accompanying the patient through the journey of healing.¹⁵
- **Achieve and maintain proficiency in the knowledge of their area of practice.** At the basic level for initial licensure, all US states require an allopathic or osteopathic medical degree, successful completion of a licensure examination, and between 1 and 3 years of postgraduate training.¹⁶ For license renewal, all US states except Colorado and South

Dakota require continuing medical education.¹⁷ At the higher clinical functioning level, all boards require postgraduate training in an approved program and successful completion of a comprehensive examination for specialty certification. All specialty boards provide time-limited certification, and all require participation in a maintenance of certification program for recent diplomates.¹⁸

- **Achieve and maintain a high level of skill in their area of practice.** At the level of the medical student, clinical skills are assessed by Step 2 (Clinical Skills) of the United States Medical Licensing Examination process.¹⁹ The Accreditation Council for Graduate Medical Education (ACGME) sets skill standards for residents and fellows-in-training.²⁰ For the practicing physician, fulfillment of this obligation of the social contract is aspirational. There is no formal organization or process for assessing and documenting clinical skills beyond clinical training, although hospital medical staff quality committees have the responsibility of monitoring procedural outcomes across a variety of specialties.
- **Provide for the patient's needs ahead of their own.** This is the fundamental expression of altruism, which is a basic tenet of all descriptions of professionalism. The modern concept of altruism is that it is not an inherent, fixed personality trait; rather, it can be objectively measured and increased by education, practice, role modeling, and reinforcement.²¹
- **Provide access to needed care.** Five steps have recently been highlighted with which physicians can advocate or act to improve access to care for the most vulnerable of our fellow Americans:
 - Ensure adequate funding of the Children's Health Insurance Program and retain Medicaid expansion and implement expansion in more states.
 - Stabilize individual insurance marketplaces and retain Affordable Care Act market reforms.
 - Address physician clinical workforce shortages.
 - Expand telehealth and remote patient monitoring.
 - Increase the efficiency of the existing workforce by instituting common-sense medical liability reforms and reducing government and insurance industry regulatory burdens such as prior authorization that detract from patient care and increase costs.²²
- **Behave with morality, integrity, and honesty within a delineated code of ethics.** Both the ACC²³ and the AHA²⁴ have established codes of ethics that define the values and behaviors required of their respective members.
- **Be trustworthy.** Patients must be confident that physicians will act not in self-interest but in the

interests of their patients. Avoidance of even the appearance of a COI is the responsibility of each physician and is a corollary to the fundamental altruistic obligation to put the patient's needs ahead of the physician's own needs.²⁵

- **Show respect for patient dignity and autonomy.** Respect for the dignity and autonomy of the patient is foundational to the practice of modern medicine. It is the legal right of patients who are properly informed and of sound mind to make the decisions directing their own care. This is an important boundary to practitioner autonomy in the practice of medicine that is imposed by the social contract.²⁶
- **Be the source of objective information and advice.** Patients expect honesty and openness from their physicians, although some data suggest that this ideal is not always met.²⁷ It may be particularly difficult when patient injury has occurred, but even in these difficult circumstances, for several reasons, honesty is the best policy.²⁸
- **Promote the public good.** In general, it is expected that physicians have a responsibility to contribute to community health-related issues beyond their duty of providing care to individual patients. Research has shown that civic-mindedness and participation in public roles are generally supported by practicing physicians.²⁹ In 2020, 17 physicians were members of the 116th US Congress (3 senators and 14 representatives).³⁰
- **Be transparent and accountable for all of the promised elements of the contract.** Transparency and accountability are the sine qua non of the physician's responsibilities under medicine's social contract. This is particularly true with respect to identifying and treating physicians who are incompetent or are emotionally or mentally impaired. The notion of this as an individual physician responsibility is supported by survey data, but the actual execution of this responsibility falls short of the ideal.³¹

1.5.2. Society Agrees to:

- **Trust medical practitioners**
- **Provide autonomy to medical practitioners**
- **Allow self-regulation for medical practitioners within legal boundaries**
- **Create and maintain a healthcare system that is**
 - Value based
 - Adequately funded
 - Reasonably flexible
- **Allow medical practitioners to have a role in the creation of public policy**
- **Require that members of society accept some responsibility for their own health**
- **Allow monopolies with reasonable boundaries**

- **Allow a balanced lifestyle for medical practitioners**
- **Provide rewards**
 - Nonfinancial rewards: respect and the presumption of benignity
 - Financial rewards

1.6. Organization of Writing Committee

The Consensus Conference attendees represented the broad range of expertise in cardiovascular medicine and a number of medical specialty organizations. This report summarizes the discussions and recommendations of that conference. The writing committee consisted of a diverse group of medical experts, including cardiologists, internists, cardiovascular team members, and a lay patient representative. The writing committee included representatives from the ACC and the AHA. Appendix 1 of the present document lists writing committee members' comprehensive RWIs.

1.7. Document Review and Publication Approval

This document was reviewed by 4 official reviewers nominated by the ACC and the AHA, as well as individual content reviewers. Reviewers' RWI information was distributed to the writing committee and is published as a table in this document (Appendix 2).

The recommendations set forth in this report are those of the conference participants and do not necessarily reflect the official position of the AHA and ACC.

1.8. Abbreviations

Abbreviation	Meaning
ACC	American College of Cardiology
ACGME	Accreditation Council for Graduate Medical Education
AHA	American Heart Association
AMA	American Medical Association
AUC	appropriate use criteria
CMS	Centers for Medicare & Medicaid Services
COI	conflict of interest
CPG	clinical practice guideline
DEIB	diversity, equity, inclusion, and belonging
EHR	electronic health record
GME	Graduate Medical Education
HIT	health information technology
HSR	human subjects research
NAM	National Academy of Medicine
RWI	relationship with industry
SDM	shared decision making
URIM	underrepresented in medicine

2. TASK FORCE REPORTS

2.1. Task Force 1: Navigating Conflicts: RWIs and COIs in Teaching and Publications, Peer Review, Research Data, Technology, and Expert Testimony

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This task force section addresses interests a healthcare practitioner, a researcher, or other healthcare professionals might have that could give rise to a potential COI and biased decision making. These include relationships the practitioner has with industry, academic institutions, healthcare systems, professional organizations, research institutions, advisory bodies, other entities, and other individuals in addition to their own intellectual interests. A COI is set of circumstances that create a risk that professional judgment or actions concerning a primary interest could be influenced by a secondary interest²⁵ or that have the appearance of having the potential to create such a risk. A primary interest varies according to the purpose of a professional activity, but for physicians and researchers in their professional roles, it includes promoting and protecting the welfare of patients, the integrity of research, and the quality of medical education. Physicians and researchers exercise judgment and discretion in their work, and their primary interests are sometimes stated as ends or goals (eg, promotion of patient welfare), as obligations (eg, the physician's obligation to promote patient welfare), or as rights (eg, the patient's right to have the physician promote his or her welfare).²⁵ A secondary interest can include not only the potential for financial gain from financial interests such as an RWI but also relationships between individuals (from friends and family to students and colleagues)²⁵ or an intellectual interest. A 4-step process (described graphically in Figure 3) is essential to considering whether a practitioner's interests create a COI and, if so, effectively managing it:

1. **Full disclosure** of RWIs, individual relationships, and any relevant intellectual interests, ensuring full transparency of the endeavor;
2. **Assessment** of those relationships by an objective body to determine whether any disclosures create an actual or apparent COI;
3. **Management** by an oversight body of any COIs in a way that protects the integrity of the endeavor; and

- Oversight** of the process by completely independent organizational personnel to ensure compliance.

This section discusses this process as it applies to associational and intellectual interests and in the context of educational activities, publications, peer review, research data, technology, and expert testimony. The many other contexts in which an interest can create COIs are beyond the scope of this section. The task force supports the existing relevant policies and guidelines of the ACC and AHA, National Academy of Medicine (NAM), ACGME, AMA, and National Institutes of Health, all of which have been carefully created and vetted,³² and makes recommendations that merit further consideration in the implementation of this process.

2.1.1. Recommendations Related to Disclosure of RWIs in Educational Activities and Scientific Publications

1.	Disclosure of RWIs should be mandatory for educational activities and scientific publications.
2.	Comprehensive current RWI disclosures should be collected and assessed by organizations for individuals involved in educational activities and scientific publications.
3.	The ACC and AHA should educate their members and promote compliance with the applicable policies ^{33,34} and other organizational publications on RWIs as they relate to educational activities and publications.
4.	The ACC and AHA should have oversight bodies and personnel in place to independently and objectively assess, manage, and oversee the integrity of any endeavor in accordance with applicable laws, industry standards, and best practices.

1. Disclosure of RWIs should be mandatory for educational activities and scientific publications.

Rationale: Not all RWIs constitute a COI. For that reason, the term *RWI* is generally preferred over the term *COI* when describing a relationship with an entity.³⁵ When a disclosed RWI is assessed and determined to be an actual or apparent COI, appropriate management of the COI can be established. Strict ACC and AHA policies are in place for reporting RWIs in as transparent a manner as possible and assessing and managing them so as to avoid the appearance or actual effect of unduly influencing ACC and AHA policies, educational activities, and publications.³⁶ Similar standards for disclosing RWIs extend outside of publications to cover practitioner responsibilities within healthcare organizations and governmental advisory groups, among others. Although not unanimous, there is a reasonable consensus that RWI data should be collected for the 12 months before such activities, a timeline consistent with the Accreditation Council for Continuing Medical Education’s Standards for Commercial Support for educational activities.³⁴

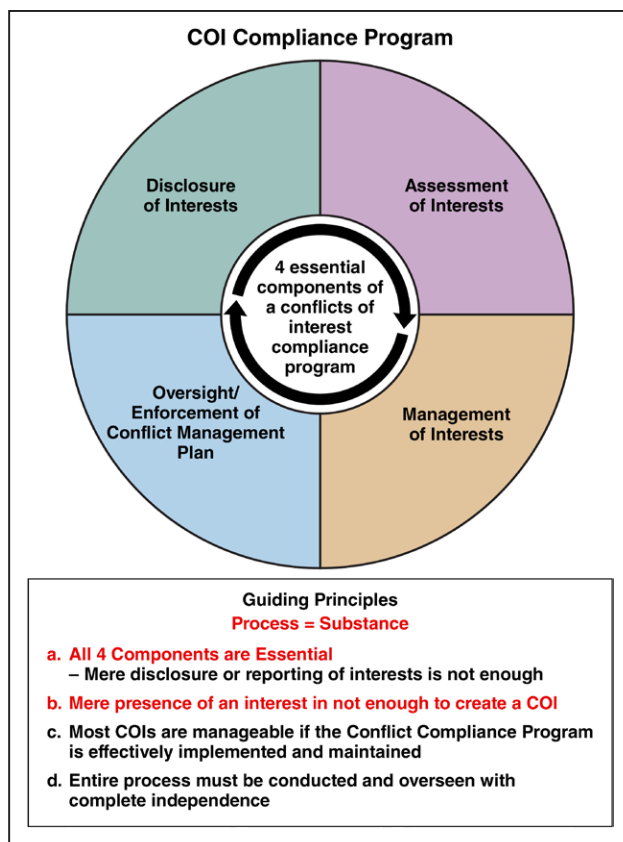


Figure 3. Conflict of interest (COI) compliance program.
Source: Bernadette M. Broccolo, Esq, McDermott Will & Emery, LLP 2020.

Current ACC/AHA policies³⁶ state that a relevant RWI is present when:

- The relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; or
- The company or entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document or makes a drug or device that competes for use with a product addressed in the document; or
- The person or a household member has a reasonable possibility of financial, professional, or other personal gain or loss as a result of the issues or content addressed in the document.

To what degree a particular relevant RWI might constitute a COI remains unclear,³⁵ and the AHA and the ACC should consider providing more specific guidance for when an RWI becomes a COI.

2. Comprehensive current RWI disclosures should be collected and assessed by organizations for individuals involved in educational activities and scientific publications.

Rationale: The collection and maintenance of current RWI data at the organizational level enhance accurate assessment of RWIs and transparent public

disclosure to medical and lay communities when practice-related and other documents are formulated and published. RWIs are dynamic and require periodic updating in accordance with existing ACC and AHA mechanisms.

3. The ACC and AHA should educate their members and promote compliance with the applicable policies^{33,34} and other organizational publications on RWIs as they relate to educational activities and publications.

Rationale: All practitioners should adhere to national organization guidance on appropriate professional conduct with respect to RWIs. Practitioners and professional organizations should endorse current AMA recommendations “to preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession.”³³ Thus, clinicians should:

- Decline monetary or other gifts in any amount from an entity that has a direct interest in physicians’ treatment recommendations;
- Decline any gifts for which reciprocity is expected or implied; and
- Accept an in-kind gift for the clinician’s practice only when the gift:
 - Will directly benefit patients, including patient education; and
 - Is of minimal value.

The 2004 “ACC/AHA Consensus Conference Report on Professionalism and Ethics”⁴ addressed issues related to relationships with commercial interests in detail, including issues related to educational activities and publications. In 2014,³⁴ the Accreditation Council for Continuing Medical Education published detailed minimum compliance requirements for continuing medical education activities. Other organizations, including the ACGME,³⁷ the NAM,³⁸ and the AHA/ACC,³⁶ have similarly updated or published new guidance for RWIs as they relate to education or publications. The 2004 report recommended that the ACC and AHA develop uniform, secure databases, updated yearly, containing full disclosure of RWIs for individuals participating in ACC and AHA educational activities and scientific publications. Both organizations have done this and have developed RWI definitions, policies, and procedures specifically as RWIs relate to the development of guidelines, performance measures, and data standards.³² Organization-specific RWI policies for other organization-specific documents are similar to these criteria.^{39,40} These policies provide helpful definitions for practitioners serving as consultants, principal investigators, speakers, employees, beneficiaries of industry grants to their institutions, and expert witnesses;

holding equity positions in business entities; and engaging in other arrangements with industry.

4. The ACC and AHA should have oversight bodies and personnel in place to independently and objectively assess, manage, and oversee the integrity of any endeavor in accordance with applicable laws, industry standards, and best practices.

Rationale: A formal process with a conflict management plan needs to be firmly in place for the management and oversight of potential COIs and RWIs. The conflict management plan addresses, for example, what information and to whom a COI should be disclosed; any needed changes in personnel or participation required; and whether the person with a COI should be screened or blinded from certain roles in the endeavor. The conflict management plan should include initial and periodic compliance reports and ongoing disclosures during the course of the endeavor; it should decide the need for an independent oversight committee and determine sanctions for compliance failures.

2.1.2. Recommendations Related to Associational and Intellectual Interests



1.	An associational interest should be fully disclosed and carefully assessed to determine whether the holder of the interest has a COI that would disqualify the holder from participating in an organizational activity; if participation is allowed, a plan for managing the COI should be developed, implemented, and enforced.
2.	An intellectual interest should be fully disclosed any time it is relevant to the matter under consideration and carefully assessed to determine whether the holder of the interest has a COI that would disqualify the holder from participating in an organizational activity; if participation is allowed, a plan for managing the COI should be developed, implemented, and enforced.

1. An associational interest should be fully disclosed and carefully assessed to determine whether the holder of the interest has a COI that would disqualify the holder from participating in an organizational activity; if participation is allowed, a plan for managing the COI should be developed, implemented, and enforced.

Rationale: An associational interest is an interest that arises from an individual’s formal or informal, nonfinancial participation in or relationship with an organization or an individual. For example, such an interest can arise from the individual’s fiduciary or official relationship with an organization or from a relationship with a person who can exercise substantial influence over the individual. These interests occur over an extremely broad landscape encompassing professional, business, social, and personal relationships, each of

which can create potential for bias. Although identifying associational interests can be challenging, their full disclosure promotes transparency and enhances the ability to assess effectively the interests for COIs. Even if the assessment concludes that an associational interest creates no actual COI, the circumstances of the interest may create the appearance of a COI that will require careful management. In situations with high risk of bias or broad clinical impact, an individual with a relevant associational COI should not be included in the relevant decision-making group. If the involvement of such an individual is essential (eg, because of unique content expertise), his or her role in the group should be limited to a nonvoting, ad hoc consulting role or otherwise managed to prevent biased influence.³⁶

2. An intellectual interest should be fully disclosed any time it is relevant to the matter under consideration and carefully assessed to determine whether the holder of the interest has a COI that would disqualify the holder from participating in an organizational activity; if participation is allowed, a plan for managing the COI should be developed, implemented, and enforced.

Rationale: An intellectual interest is a strongly held opinion, belief, or position or a strong desire to protect or advance such an opinion, belief, or position. These interests can arise in many circumstances such as when:

- A renowned scientist's career has been based on a particular long-held concept, hypothesis or clinical procedure; or
- A department chair inappropriately advances or impairs the career of another person with whom the chair disagrees without an independent, objective evaluation of the scientific quality or the value of the proposed work or action; or
- An editor makes an adverse decision concerning the publication of an article that does not align with personal interests or beliefs but may be misconstrued as publication bias or, contrarily, over-promotes publications that align with the editor's personal beliefs.

Like associational interests, intellectual interests can be difficult to identify, even by the individuals involved, and require the knowledge of disinterested individuals or organizations who are familiar with the holder of such interests. Despite these obstacles, intellectual interests should be identified, fully disclosed, and carefully assessed to determine whether they give rise to a COI or the appearance of a COI. If COIs exist, they should be carefully managed. In situations with high risk of

bias or broad clinical impact, an individual with a relevant intellectual COI should not be included in the relevant decision-making group. Examples to ensure that there is not a high risk of bias include decisions about promotions, grants, and guideline recommendations or editorial decisions. If the involvement of such an individual is essential (eg, because of unique content expertise), his or her role in the group should be limited to a nonvoting, ad hoc consulting role or otherwise managed to prevent biased influence.³⁶

2.1.3. Recommendations Related to External Assessments of Interests

1.	Open Payments reports of a single instance of in-kind food and beverage of <\$100 or aggregate food and beverage from a company of <\$500 should not generally be labeled as an RWI or COI.
2.	Open Payments reports of significant payments to an individual that are not self-reported during the organizational vetting process should trigger an assessment of this discrepancy. A formal process should be established for such assessment and, if necessary, management.

1. Open Payments reports of a single instance of in-kind food and beverage of <\$100 or aggregate food and beverage from a company of <\$500 should not generally be labeled as an RWI or COI.

Rationale: The Physician Payments Sunshine Act requires industry to report in the Centers for Medicare & Medicaid Services (CMS) Open Payments database receipt by a practitioner of any meal provided or paid for by industry and valued at >\$10. Current ACC/AHA policy on RWIs, as they relate to the development of guidelines, performance measures, and data standards,³² states that AHA or American Stroke Association staff will review the Open Payments database for any disclosures applicable to committee members during formation of the writing committee and every 6 months thereafter through publication. However, the ACC and AHA have established no official policy for addressing discrepancies between self-reported RWIs and Open Payments reports.

The existence of an external listing of payments to physicians has presented both new opportunities and challenges in assessing RWIs. Although the intent of the Physician Payments Sunshine Act was to provide greater transparency for the public, the Open Payments website provides potential additional information beyond self-reporting that can be used to assess RWIs. However, in some cases, reported data may be inaccurate^{32,39} but not deemed by practitioners worthwhile in terms of time and effort to dispute. Practitioners who wish to dispute reported data would have to check the database

regularly and then undertake a cumbersome and time-consuming administrative process. Even when accurate, it can be argued that such financial interactions will not materially influence how a recipient will objectively assess and interpret clinical data and formulate conclusions and recommendations. Although 1 study reported a modest correlation between the receipt of industry-sponsored meals and prescribing patterns,⁴⁰ it is still unclear to what degree, if any, such occurrences would lead to true bias in decision making and whether such modest interactions constitute an RWI or COI. Furthermore, addressing a potentially large number of such listings could obscure more substantial reported financial relationships and divert attention and limited resources from addressing those RWI discrepancies that truly merit vetting.

In any event, the experience of some reputable academic medical centers has shown that, regardless of whether incidental connections with industry are influential, the appearance that they might be influential is enough to create regulatory and public relations sanctions. Therefore, the ACC, AHA, and similar professional organizations should work with external regulatory bodies to establish, as a matter of law, that <\$100 in value for any 1 reported RWI and <\$500 in value for RWIs with any 1 company would not constitute a COI. It is also acknowledged that the effects of the number of industry-practitioner contacts, independently of any actual financial support, could potentially influence a practitioner's behavior. This deserves further consideration by the ACC and AHA.

2. Open Payments reports of significant payments to an individual that are not self-reported during the organizational vetting process should trigger an assessment of this discrepancy. A formal process should be established for such assessment and, if necessary, management.

Rationale: To assess accurately potential relevant RWIs and COIs, appropriate organizational staff should vet significant discrepancies between what is self-reported and what is reported on the Open Payments website. The Open Payments data may be inaccurate; the practitioner may not have realized or remembered receiving compensation; or a true unreported discrepancy may exist. It may be best that the findings from such vetting are reported in the forms of asterisk or supplemental appendixes along with the published documents.

2.1.4. Recommendations Related to Research, Publication, Educational Activities, and Implementation Ethics

1.	Comprehensive individual and institutional RWI data should be uniformly and carefully collected and disclosed for all investigators participating in HSR. For financial COI, threshold levels should be set for allowance of HSR participation based on the types of relationships and the role of the individual in the research.
2.	All HSR should have a mechanism of completely independent oversight that includes institutional review boards and data safety monitoring boards.
3.	All HSR, particularly clinical trials, should include a prospective plan for publication of the results in a timely fashion after completion of the project, regardless of the results of the research.
4.	All publications arising from HSR should be fair and balanced presentations of the available data and should be accompanied by a transparent and complete listing of all authors' roles in the research. Authorship for all HSR should follow the recommendations and requirements of the International Committee of Medical Journal Editors. Any individual compensated to draft or edit a publication should be listed either as a coauthor or in the acknowledgments section of the article.
5.	The dissemination of knowledge through educational programming, when following formal continuing medical education formats as well as nonregulated programming, should be developed using the best available science and evidence.
6.	Both institutions and physicians should separate discussions with patients about philanthropy from conversations and decision making concerning a patient's clinical care so that patients receive medically necessary care and the care delivery is not influenced by a patient's financial means or whether a patient does or does not make a gift.

1. Comprehensive individual and institutional RWI data should be uniformly and carefully collected and disclosed for all investigators participating in HSR. For financial COI, threshold levels should be set for allowance of HSR participation based on the types of relationships and the role of the individual in the research.

Rationale: Clinical research, especially that dealing with diagnostic tests and therapeutic agents, is often funded by businesses that manufacture drugs and medical devices. Biases arising from RWIs may exist in the design and implementation of clinical trials to evaluate the potential risks and benefits of medical products. Understanding these biases and the perspective of the investigators can help in the interpretation of the published study reports. At some threshold of financial or intellectual COIs, the real or perceived biases should limit an individual's role in a clinical research project, especially in an investigator role that interacts directly with human subjects.

2. All HSR should have a mechanism of completely independent oversight that includes institutional review boards and data safety monitoring boards.

Rationale: HSR is performed using an ethical framework intended to protect individual participants' rights. Thus, it is critical that all HSR has independent, conflict-free oversight mechanisms to ensure the safety of individuals and the integrity of the research. This oversight is the fourth element of an effective COI compliance program and should include institutional review boards and data safety monitoring boards as part of an institution's overall compliance effort. All HSR should be subject to this oversight, and most HSR, especially studies of therapeutic interventions, should have a pre-stated safety and monitoring plan that functions independently of the investigators and the research sponsor. Particular care should be taken when an industry sponsor is involved in HSR, including clinical trials of medical products being studied for possible commercial use. Appropriate safeguards must be in place to protect the integrity of the research from data manipulation, including falsification and removal of study information. Appropriate policies and procedures concerning data integrity should be prospectively stated and periodically monitored for compliance.

3. All HSR, particularly clinical trials, should include a prospective plan for publication of the results in a timely fashion after completion of the project, regardless of the results of the research.

Rationale: An essential component in the ethical conduct of all HSR is the unwavering commitment to transparently disseminate knowledge through public presentation and publication in peer-reviewed journals. Plans for publication should proceed whether the trial results in positive, neutral, or negative findings because all HSR should be considered potentially informative. Consideration of the timing of public disclosure of HSR results may be influenced by intellectual property concerns and financial reporting obligations, but these issues cannot supersede the ethical obligation for sharing knowledge and full transparency in public results reporting.

4. All publications arising from HSR should be fair and balanced presentations of the available data and should be accompanied by a transparent and complete listing of all authors' roles in the research. Authorship for all HSR should follow the recommendations and requirements of the International Committee of Medical Journal Editors. Any individual compensated to draft or edit a publication should be listed either as a coauthor or in the acknowledgments section of the article.

Rationale: There should be a full disclosure of HSR results that follows a prospective plan for statistical analyses and the reporting of results, including according to prespecified primary, secondary, and exploratory endpoints. Authorship for all HSR should follow the recommendations and requirements of the International Committee of Medical Journal Editors, as defined in its document, "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals."⁴¹ Neither guest nor ghost authorship is appropriate in HSR publications. Guest authors have not participated, in any meaningful way, in the conduct of the research or in the presentation and publication of the results. Ghost authors, who are not listed as actual authors on a publication, can sometimes draft or write substantial portions of a publication and are frequently compensated medical writers who were not involved in the conduct of the research. The ethical approaches maintained in traditional publications should also be adhered to in nontraditional communications such as social media platforms, blog posts, podcasts, and radio and television.

5. The dissemination of knowledge through educational programming, when following formal continuing medical education formats as well as nonregulated programming, should be developed using the best available science and evidence.

Rationale: Limiting bias and publicly disclosing potential biases are critical steps toward providing educational programming that is fair and based on the best available scientific evidence. Although not all educational programming is intended to be delivered in a regulated environment, similar concepts should still apply so that the consumers of all educational programming find it trustworthy.

6. Both institutions and physicians should separate discussions with patients about philanthropy from conversations and decision making concerning a patient's clinical care so that patients receive medically necessary care and the care delivery is not influenced by a patient's financial means or whether a patient does or does not make a gift.

Rationale: Patient philanthropy is an importance source of support for healthcare institutions. The AMA Council on Ethical and Judicial Affairs states:

If they do not shift the focus of the patient-physician relationship away from the patient's welfare and are conducted in a manner that respects patients dignity and rights, and benefits of the community, solicitation activities can constitute an appropriate use of physicians' influential role in society.⁴²

A survey of US patients found that "83% strongly agreed or agreed that physicians talking with their

patients about donating may interfere with the patient-physician relationship."⁴³ The ethical practitioner must acknowledge the inherent vulnerability of patients and the importance of trust in the patient-practitioner relationship. To minimize the risk of potential interference in the patient-clinician relationship, further donor solicitation ideally should be immediately relegated to the institution's development division. The presence of patient philanthropy should not undermine obligations to ensure equity in the healthcare experiences of all patients, independently of their financial means.

2.1.5. Recommendations Related to Peer Review and Grant Study Sections

1.	Peer review of publications is a cornerstone of the process of advancing science and clinical medicine through the dissemination of knowledge. Therefore, members of the science community should participate in peer review as an important service responsibility.
2.	It is critically important to declare financial or nonfinancial secondary interests before agreeing to review a manuscript. Disinterested journal editors should put those competing interests into context and balance the need to have the reviewer's expertise against the inherent biases in those competing interests.
3.	Peer reviewers should be fair and balanced in their critiques, mindful of their own biases, and timely in their reviews. Strict confidentiality throughout the entire review process, beginning with the invitation phase and extending throughout the review and grant notification period, is critical for fairness and trust in the grant review system.
4.	Scientists and laypeople invited to participate in a grant study section should be aware of policies of the granting agency on RWIs and COIs and disclose all relevant secondary interests to responsible grant administrators before accepting the responsibility to serve.
5.	Reviewers who have been accepted to participate in a grant study section should follow the granting agency's policies governing secondary interests throughout the review process, including reporting new secondary interests that might arise during their period of service on that study section.

1. Peer review of publications is a cornerstone of the process of advancing science and clinical medicine through the dissemination of knowledge. Therefore, members of the science community should participate in peer review as an important service responsibility.

Rationale: Science and clinical medicine advance through discovery, dissemination of knowledge, and the implementation of that knowledge in an applied way. Key to this system is peer review in the publication process. Peer review protects the integrity of science by independently reviewing the details of scientific discovery as part of the editorial process. Scientists, clinicians, and scholars should participate in peer review as part of their service to the community.

2. It is critically important to declare financial or nonfinancial secondary interests before agreeing to review a manuscript. Disinterested journal editors should put those competing interests into context and balance the need to have the reviewer's expertise against the inherent biases in those competing interests.

Rationale: Trust in the peer-review system helps maintain the integrity of medical and scientific publications. Authors need to trust that reviewers approach their work with transparency and fairness, and readers need to know that editors exercised unbiased judgment and considered and resolved any relevant secondary interests of authors and reviewers before accepting and publishing the manuscript. Financial interests might include research funding, consulting compensation, or equity from sponsors or competing sponsors of the submitted work. Nonfinancial interests (associational or intellectual) can be more difficult to identify. Editors have a duty to consider and weigh the inherent biases in these interests throughout the review process and to determine what minority percentage of potentially biased reviewers may be needed to achieve a high level of expertise in the review committee. Additional unbiased peer reviewers might be necessary to provide balance and a fair process.

3. Peer reviewers should be fair and balanced in their critiques, mindful of their own biases, and timely in their reviews. Strict confidentiality throughout the entire review process, beginning with the invitation phase and extending throughout the review and grant notification period, is critical for fairness and trust in the grant review system.

Rationale: All reviewers should be aware of the beliefs and biases they bring to their critique of submitted scientific manuscripts, abstracts, or other scholarly submissions and of the need to be fair and balanced in their reviews. Timeliness in the review process is as critical as attention to confidentiality until the submitted work is made public. Reviewers should not use the insights gained from prepublication reviews to further their own interests, particularly their own research, or efforts from interested third parties, including any medical product companies from which a reviewer receives research funding or consulting fees.

4. Scientists and laypeople invited to participate in a grant study section should be aware of policies of the granting agency on RWIs and COIs and disclose all relevant secondary interests to responsible grant administrators before accepting the responsibility to serve.

Rationale: A competitive research grants system depends on the willingness of fellow scientists and laypeople to

provide critical review and appraisal of submitted applications so that the most meritorious work receives funding. The integrity and fairness of the process require that reviewers approach their task free of personal, professional, or institution relationships that may be considered COIs. Each granting agency has policies and procedures for the disclosure and management of potential COIs before acceptance of a role on a grant study section. Typically, professional research administrators handle assessment of these disclosures, adhering to applicable policies. Disclosures of highly complex individual or institutional interests may require the oversight of higher-level managers in the institution's compliance program.

5. Reviewers who have been accepted to participate in a grant study section should follow the granting agency's policies governing secondary interests throughout the review process, including reporting new secondary interests that might arise during their period of service on that study section.

Rationale: Because trust is critical in a merit-based grant review process, it is important to be proactive in declaring any COI that might develop during the tenure of a grant study section.

2.1.6. Recommendations Related to Expert Testimony and Opinions

1.	Organizations should maintain requirements for ethical, truthful, clear, science-grounded, and conflict-free expert medical testimony in civil and criminal litigation.
2.	Organizations should establish a practical mechanism for conducting single-specialty or multispecialty prospective peer review of proposed expert medical testimony in civil and criminal litigation.

1. Organizations should maintain requirements for ethical, truthful, clear, science-grounded, and conflict-free expert medical testimony in civil and criminal litigation.

Rationale: The AHA and ACC have established ethics standards that apply to expert testimony given by their members, volunteers, and employees.²³ These standards help to promote and maintain expert testimony that supports the fair and equitable administration of justice. The consensus among medical professional organizations is that medical opinions rendered in civil and criminal litigation should have the characteristics set out in Table 1.^{4,44,45} Professional organizations should continue to support these standards and sanction members who fail to meet them.

2. Organizations should establish a practical mechanism for conducting single-specialty or multispecialty prospective peer review of proposed expert medical testimony in civil and criminal litigation.

Table 1. Characteristics of Effective Expert Testimony in Civil and Criminal Litigation

Truthful and furthers the cause of justice
Fair, accurate, and impartial without advocacy for any party to the litigation
Rendered by a physician who is board certified within his or her area of practice, has a valid, unrestricted license to practice, is actively engaged in that area of practice, and is an acknowledged expert in the area in question
Limited only to matters within the physician's clinical specialty and expertise
Objective and scientifically based
Based on all relevant documentation
Rendered in accordance with generally accepted standards of practice at the time in question
Willing to be provided to plaintiffs and prosecutors or defendants
Provided for reasonable compensation not contingent on the outcome of the case
Clarity as to whether testimony is offered as the physician's individual opinion or as the position of a professional association or other organization
If provided on behalf of a professional association or other organization, free of any COIs

COI indicates conflict of interest.

Rationale: How can the ACC, AHA, and other professional organizations more vigorously promote effective expert testimony in civil and criminal litigation? Despite general agreement on the necessary characteristics of ethical expert testimony, misleading, unscientific, and unethical testimony still occurs.^{46–48} Trial judges are responsible for determining whether the underlying reasoning or methodology of the expert testimony is scientifically valid and can be applied properly to the facts at issue.^{49,50} However, judges do not have the necessary knowledge to make such a determination independently. Therefore, professional associations and independent review organizations need an effective method of assessing whether expert testimony supports the cause of justice and enables a judge to make an informed ruling concerning its admissibility. Although several professional organizations have established procedures for retrospective peer review of expert testimony given by their members, such review occurs only on the filing of a complaint with the organizations' ethics or disciplinary committees.⁵¹ Any damage or injustice incurred by a party to the litigation as a result of inappropriate testimony at trial will have occurred already and is not likely to be remedied. Therefore, a posttrial determination that a breach of ethics occurred or that the expert in question was incompetent to testify will not further the cause of justice in that case. A prospective peer review that is tailored to the requirements of the case in question and applies the same discipline and reliability that is firmly established in rigorous medical research funding and publication procedures would provide a useful avenue to higher-quality testimony and to better informed judicial decisions concerning the admissibility

Table 2. Benefits of Prospective Review of Expert Testimony

Introduces accountability that courts are unable to provide
Disciplines scientific evaluation throughout the trial
Promotes the quality of science introduced in court
Emphasizes quality control rather than retrospective sanctions for experts
Safeguards justice
Promotes appropriate, fair dispute settlements that can prevent injustice
Reduces grounds for appeals
Enables multidisciplinary peer review
If provided on behalf of a professional association or other organization, is free of any COIs

COI indicates conflict of interest.

of expert opinions and would generate the benefits noted in Table 2. If the facts of the case present complex scientific questions requiring multiple experts, a multidisciplinary prospective peer review of proposed testimony would achieve greater sophistication, accountability, and efficiency in the trial process.⁵²

2.2. Task Force 2: Diversity, Equity, Inclusion, and Belonging: Optimizing Cardiovascular Health Care, Research, and Education Through Equity and Respect and Eliminating Bias, Discrimination, Harassment, and Racism

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Although aspects of medical ethics and professionalism often focus on patient care, injustices in the medical profession and in society require increased attention to the quality of the workforce, including how professionals interact with each other. A growing appreciation of the essential importance of diversity in achieving excellence and recognition of the widespread prevalence and consequences of a range of behaviors and inequities from implicit bias, to discrimination and harassment, to structural sexism and racism demands action. When present, these can negatively affect education, science, patient care, and public health, as does the absence of diversity. Issues of health equity and social justice are discussed in Task Force 4 of this conference

(Patient Autonomy, Privacy, and Social Justice in Health Care). Task Force 2 considers professional and career aspects of diversity, equity, inclusion, and belonging (DEIB), as well as related systematic inequalities in treatment, power, and resources of individuals and groups. It must be recognized that this separation is somewhat artificial and that the tenets and solutions for DEIB and health equity are tightly and inextricably linked.

Underrepresentation and inequalities are pervasive in today's cardiovascular world. They have been created and are sustained by structural factors, organizational practices, individual interactions, and cultural beliefs. The impact of even severe forms of sexism, racism, harassment, and discrimination on individuals and organizations pales compared with the far more devastating and enduring effects of centuries of institutional and structural injustice in medicine. Structures, cultures, and systems need to be reconfigured to address all aspects of DEIB (Figure 4)⁵³ to effectively reduce disparities, to empower marginalized groups, and to eliminate injustice. In addition to ensuring DEIB within their own ranks, professional societies such as the ACC and AHA and the conveners of this conference have a unique voice and authority, with responsibility for guiding the profession overall.

Foundational to these concerns is the need to achieve diversity within the cardiovascular workforce and its leadership to better reflect and represent the patients and populations served. The cardiology workforce includes proportions of women and Black, Hispanic, and Native American individuals that are lower than in the US population; there has been little improvement in the past decade.⁵⁴ The ACC, AHA, and other organizations recognize the fundamental need to "benefit from a diversity of backgrounds, experiences and perspectives in leadership, cardiovascular healthcare delivery, business, education and science."⁵⁵ The current lack of diversity limits the ability to address the "diverse health needs of cardiovascular patients and populations...by cardiovascular clinicians sensitive to and prepared to meet the unique needs of their gender, cultural, racial and ethnic and other dimensions of diversity."⁵⁶

The current ACC Code of Ethics²³ and Diversity and Inclusion Governance principles (internal document) and AHA's Code of Ethics and Nondiscrimination Policy²⁴ and contract terms for research awardees (and their institutions) include strong statements proscribing discrimination, harassment, or retaliation, requiring respect, equitable treatment, and "a culture of openness, trust, and integrity."⁵⁶ The recommendations of Task Force 2 serve to supplement and augment these documents while strongly emphasizing the positive aspects of inclusion and belonging. The recommendations call for constructive, affirming change because this provides the best possible basis for eliminating negative



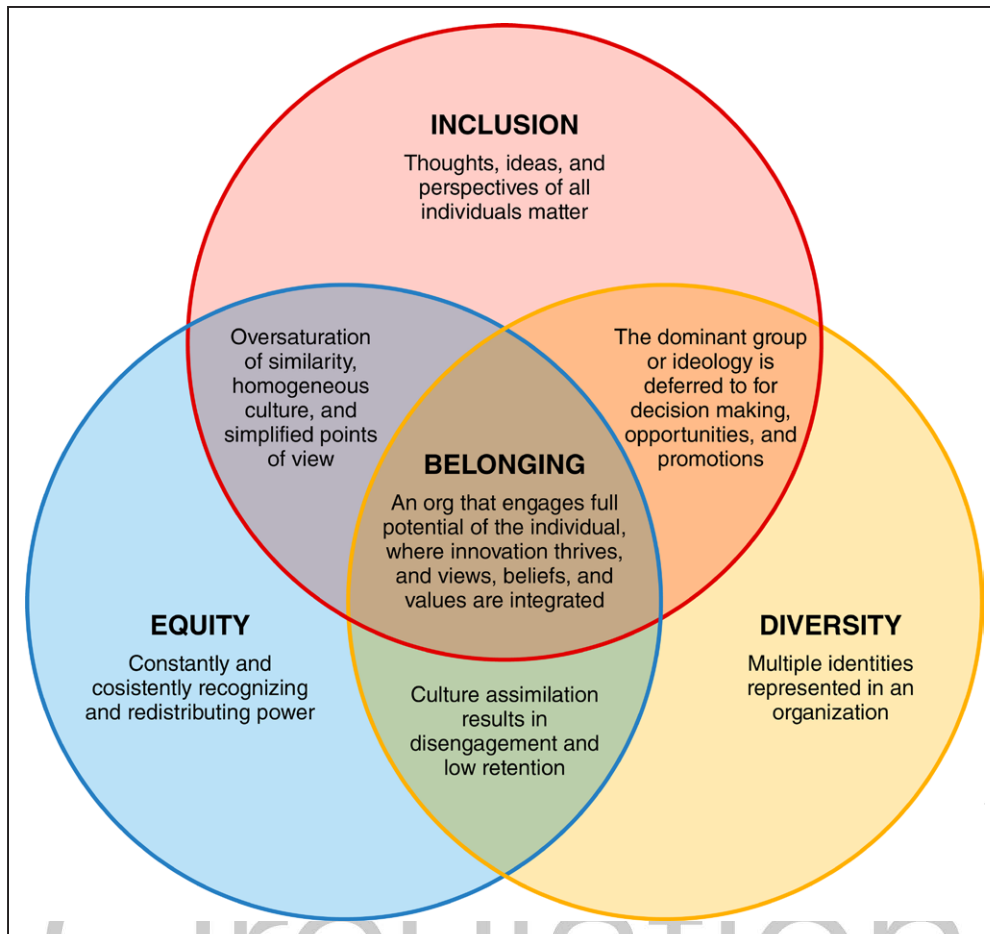


Figure 4. Integration and alignment of components of diversity, equity, inclusion, and belonging. Org indicates organization. Data derived from Burnett.⁵³

behaviors and systems and their consequences and is a requirement for a culture of inclusion and belonging (Figure 5). Achieving personal and social justice in cardiovascular health, medicine, and science requires individuals to fully value each other and for institutions to fully value each person.

Diversity and respect are essential elements in combatting negative behaviors such as harassment and discrimination but are insufficient. It is also crucial to address entrenched structural inequities such as sexism and racism. These inequalities, or indeed any systematic or structural inequity, are systems that configure opportunity and label worth and accomplishment according to certain characteristics (skin color and sex, among others) that unfairly advantage some individuals and communities and unfairly disadvantage others. These systems are present in our institutions and societal norms, as well as interpersonal interactions, and they weaken our entire community. Most important to these recommendations, they are amenable to modification and dismantling.⁵⁷ This document may serve as an initial step for larger, sustained efforts by the ACC and AHA, as well as the entire cardiovascular community.

2.2.1. DEIB: General Concepts

1.	Diversity is the recognition that variety in race, ethnicity, sex, and other characteristics brings the top talent and experience necessary to advance the art and science of cardiovascular health.
2.	DEIB are collectively and individually essential to excellence and therefore must be incorporated into all strategic decisions in education, clinical care, research, and business.
3.	Immediate DEIB goals are to: <ul style="list-style-type: none"> • Achieve diversity in trainees, workforce, and leadership; • Ensure freedom from bias, discrimination, and harassment; • Ensure equity, inclusion, and belonging; and • Eliminate structural racism and sexism.
4.	The existence and perpetuation of bias and structural racial, ethnic, sex, and other inequities throughout the cardiovascular community must be recognized and acknowledged as a problem, and change must be embraced and incentivized as vital to mission.
5.	Efforts to address DEIB must be leader led and evidence based and use a systems approach to change that is tied to measurable outcomes. Efforts must use quality improvement principles and be well resourced and visible, with transparent sharing of progress and best practices (see Section 2.2.4.).

1. Diversity is the recognition that variety in race, ethnicity, sex, and other characteristics brings the top talent and experience necessary to

advance the art and science of cardiovascular health.

Rationale: Diversity goes beyond skin color, race, ethnicity, and sex to include age, socioeconomic background, disability status, gender identity, sexual orientation, religion, and class, among others. Diversity requires inclusion of individuals with varied “backgrounds, experiences, and perspectives in leadership, cardiovascular healthcare delivery, business, education, and science”²³ who bring a range of perspectives and approaches.

Rigorous quantitative and qualitative assessments of institutional diversity are required to attain excellence, and deliberate strategies to improve representation may reduce discrimination, cultural marginalization, and denial of access. At present, quantification of dimensions of diversity and the use of targets for equity are warranted to correct current severe disparities and to address the urgent need to increase representation. These strategies neither imply nor require any compromise in competence or quality, either in individuals or in the cardiovascular workforce. In fact, the opposite is true; efforts to include more diverse individuals are an important opportunity to improve the entire workforce by adopting contemporary holistic review approaches.⁵⁸ It is also an opportunity to challenge inherently flawed definitions of quality, including those based on biased instruments such as standardized testing, and to ensure recognition of important characteristics such as cultural competency, empathy, and communication, some of which may be exemplary among women and those who are underrepresented in medicine (URIM). Recognition of potential for achievement is also critical to evaluating talent in those who have experienced systematic exclusion arising from pervasive structural discrimination, sexism, and racism in society and medicine.

2. DEIB are collectively and individually essential to excellence and therefore must be incorporated into all strategic decisions in education, clinical care, research, and business.

Rationale: Substantial evidence in business, medicine, and science shows that diversity is associated with improved individual, team, and organizational performance.⁵⁹ Diversity is also associated with improved science: Author racial and ethnic diversity increased impact by up to 11% across >9 million publications and by up to 48% across >6 million scientists.^{60,61} A recent review of the education, healthcare, and business sectors revealed that diversity (including race, ethnicity, sex, and age) improved clinical and educational outcomes, organizational strategy, effective communications, innovation, and financial metrics.⁶² Without embracing DEIB, a center cannot claim true excellence. Because diversity adds value to all sectors of health care, ignoring it will greatly weaken the community.

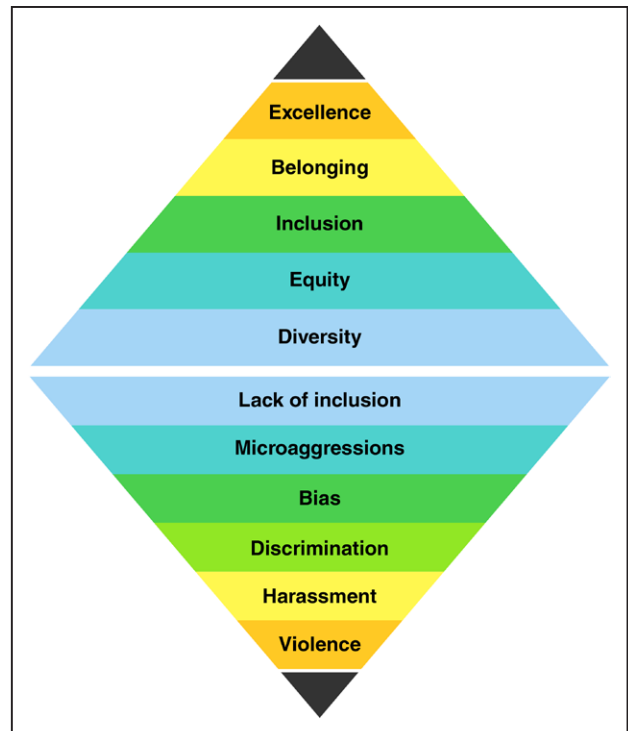


Figure 5. Continua of adverse and positive behaviors.



3. Immediate DEIB goals are to:

- Achieve diversity in trainees, workforce, and leadership;
- Ensure freedom from bias, discrimination, and harassment;
- Ensure equity, inclusion, and belonging; and
- Eliminate structural racism and sexism.

Rationale: Constructive, affirming change requires emphasis on the positive aspects of inclusion and belonging as the best possible basis for eliminating negative behaviors and systems and their consequences. Deliberately removing institutional and individual barriers and addressing structural injustice are elemental,⁵³ yet an environment of genuine respect and concern for others is not sufficient to eliminate sexism and racism. Comprehensive and enduring solutions require achievement of inclusion and belonging, as well as diversity and equity (Figure 4).

4. The existence and perpetuation of bias and structural racial, ethnic, sex, and other inequities throughout the cardiovascular community must be recognized and acknowledged as a problem, and change must be embraced and incentivized as vital to mission.

Rationale: Recognizing the existence of structural inequities, acknowledging them to be a problem, and reconciling past and present harms are essential in building an equitable future.^{63,64} To this end, the Association of American Medical Colleges recommends these essential initial steps: appreciate the historical context and true impact of exclusionary practices on current-day

institutions; refuse to blame individuals for these inequities but rather look to the failure of institutional support; and recognize the importance of intentionality and deconstruction of structures, governance, policies, practices, and embedded norms and values that sustain inequities.⁶⁵

5. Efforts to address DEIB must be leader led and evidence based and use a systems approach to change that is tied to measurable outcomes. Efforts must use quality improvement principles and be well resourced and visible, with transparent sharing of progress and best practices (see Section 2.2.4.).

Rationale: DEIB are not easily achieved, yet there are examples of successful interventions (Table 3). The National Academies of Sciences, Engineering, and Medicine note the following requirements for success:

1) committed leadership at all levels; 2) dedicated financial and human resources; 3) a deep understanding of institutional context; 4) accountability and data collection—especially as a tool to inform and incentivize progress; and 5) adoption of an intersectional approach that explicitly addresses challenges faced [by those] who encounter multiple, cumulative forms of bias and discrimination.⁷¹

To hold leaders and their organizations accountable, meaningful DEIB metrics must be developed, measured, and reported across all educational, clinical, and scientific activities.

2.2.2. Specific Accountabilities and Special Groups

1.	Cardiovascular clinical, academic, organizational, and specialty society leadership and organizations must be held accountable for institutional culture and for visibly championing, working toward, and achieving DEIB.
2.	Individuals must openly value DEIB and be role models in actively working to mitigate implicit bias and to eliminate unprofessional behaviors, sexism, and racism in their interactions and work environments.
3.	Educators have a special responsibility to ensure diversity among those entering the cardiovascular community and to eliminate bias, sexual harassment, and racism in schools and training programs.
4.	Senior educators, clinicians, researchers, and leaders must provide professional development, mentorship, and sponsorship at all career stages for marginalized individuals who are URIM and for women, recognizing biases toward the more familiar, visible achiever.
5.	The presence and inclusion of women and other individuals who are URIM among students, trainees, and leadership are particularly critical and therefore merit special attention.

1. Cardiovascular clinical, academic, organizational, and specialty society leadership and organizations must be held accountable for institutional culture and for visibly championing, working toward, and achieving DEIB.

Rationale: “Uninformed leadership...that lacks the intentionality and focus to take the bold and aggressive measures needed” is an important factor in limiting success.⁷¹ Leaders in cardiovascular medicine must ensure that they, personally, and their organizations, institutionally, provide a sense of belonging for all, not just in words but in specific actions.⁷² They are responsible for actively questioning the influence of racism and sexism throughout their organizations and for working to dismantle them. Recommended actions include exploring organizational structure, setting clear expectations for behavior, identifying areas of vulnerability, creating structures to encourage reporting of events, and establishing accountability policies that include those in positions of power. Organizations may consider establishing policies and enforcing them by board-level reviews and tying rewards (eg, compensation, promotion) to adherence, with sanctions (eg, compensation reduction, demotion, termination) for nonadherence.⁷²

2. Individuals must openly value DEIB and be role models in actively working to mitigate implicit bias and to eliminate unprofessional behaviors, sexism, and racism in their interactions and work environments.

Rationale: Each individual is responsible for understanding and mitigating their own biases and for ensuring that all personal and observed behaviors and language are consistent with DEIB. Biased behaviors carry negative consequences to those targeted and their colleagues.⁷³ The specific circumstances in cardiology (White, male dominated; male normative models and values; historical tolerance for harassment and exclusionary behaviors; hierarchical leadership) are well-documented risk factors for harassment, which leads to less engagement and higher attrition. Visibly practicing allyship, including expanding affirmation behaviors such as “upstander” interventions and active implementation of DEIB policies,⁷⁴ is essential to moving DEIB from private to public support. Individuals have a duty to inform, educate, and advocate, ensuring that policy makers, regulators, and legislators promote DEIB in public policy and support efforts that advance DEIB (eg, public education and removing legislative barriers).

3. Educators have a special responsibility to ensure diversity among those entering the cardiovascular community and to eliminate bias, sexual harassment, and racism in schools and training programs.

Rationale: It is especially important for cardiovascular educators to ensure the diversity of those coming into the field. Innovative recruitment strategies successfully deployed by other specialties to attract top talent from diverse backgrounds must be considered, including shortening the duration of training by integrating residency and fellowship.⁷⁵ Cardiovascular educators must also live the values of medical professionalism that they espouse to their students. Unfortunately, the current experience

Table 3. Examples of Evidence-Based Interventions to Enhance DEIB in Academia

Author	Study sample	Intervention	Outcomes
Carnes et al, ⁶⁶ 2015	Cluster-randomized trial of a sex bias intervention in 92 departments of divisions at the University of Wisconsin–Madison	Trained participants in evidence-based sex bias–breaking approaches, including stereotype replacement, counterstereotypic imaging, individuating, perspective taking, and increasing opportunities for contact with underrepresented groups	Significant improvements in: Self-efficacy to engage in sex equity–promoting behaviors ($P=0.01$) Self-reported action to promote sex equity ($P=0.07$) Greater fit ($P=0.02$) Valuing their research ($P=0.02$) Comfort in addressing professional conflicts ($P=0.03$)
Capers et al, ⁶⁷ 2017	OSUCOM, 140 medical school admissions committee members	All members took the Black/White IAT before the admissions cycle; 100 (71%) recorded their impressions at the end of the cycle	All groups had significant levels of implicit White preference: Faculty ($d = 0.82$) and men ($d = 0.70$) had largest bias 48% Endorsed awareness of their individual results when interviewing candidates 21% Reported knowledge of IAT influenced admissions decisions Class that matriculated post-IAT exercise most diverse in OSUCOM's history
Roswell, et al, ⁶⁸ 2020	Zucker School of Medicine and Northwell Health, 119 faculty and staff	Piloted 60-min microaggressions workshop, 20-min VR racism experience, group reflection	76 (68%) Participants completed postworkshop survey: 95% Stated VR enhanced their empathy 86% Stated session enhanced their empathy for racial minorities 67% Stated their communication approaches would change
Johnson et al, ⁶⁹ 1998	University of Pennsylvania, undergraduate, GME, faculty	Undergraduate: premedical enrichment program Medical student: counseling, research development, clinical course enhancements GME trainees and faculty: training in research methods, mentoring, teaching skills, and scientific writing skills	Increased the number of underrepresented minority faculty by 32% in 4 y and created an environment conducive to the professional growth and development of minority faculty
Grisso et al, ⁷⁰ 2017	University of Pennsylvania, all female assistant professors	27 Departments randomized to a multifaceted intervention: 1) Professional development of female assistant professors 2) Changes at the department and division levels through faculty-led task forces 3) Engagement of institutional leaders	Decline in work hours despite similar increases in academic productivity (“working smarter”) Greater benefit for those with PhDs than those with MDs

DEIB indicates diversity, equity, inclusion, and belonging; GME, Graduate Medical Education; IAT, Implicit Association Test; OSUCOM, Ohio State University College of Medicine; and VR, virtual reality.

of trainees is too often marred by dismissive and challenging behaviors, harassment, and exclusion, particularly for women and others who are URIM. Cardiovascular educators must address their own behaviors, must be well versed in the literature detailing these challenges,⁷⁶ and must use best practices to remedy past injustices and avoid future occurrences. Academic institutions need to support educators with structured programs for understanding and rectifying their own behaviors and to be allies to combatting these behaviors in their colleagues.

4. Senior educators, clinicians, researchers, and leaders must provide professional development, mentorship, and sponsorship at all career stages for marginalized individuals who are URIM and for women, recognizing biases toward the more familiar, visible achiever.

Rationale: Professional development programs, long proven to be important facilitators for career advancement, are essential to the success of women and those

who are URIM.⁷⁷ Although it is invaluable for senior leaders to provide personal mentorship and sponsorship for women and those who are URIM, structured mentoring programs supporting those who are URIM and women at all career stages are necessary. Mentors and sponsors must live the values of medical professionalism that they espouse to their students and mentees.

5. The presence and inclusion of women and other individuals who are URIM among students, trainees, and leadership are particularly critical and therefore merit special attention.

Rationale: Diversity of trainees is essential to reflect society, the population, and therefore talent. It is the only mechanism by which the face of the cardiovascular community can be changed over time. Without more diverse individuals in the pipeline and a clearer pathway to success, there cannot be a change in the workforce. At present, both male and female internal medicine residents are dissuaded from choosing cardiology careers

by perceptions that the profession does not offer stable hours or a family-friendly environment⁷⁸; this culture must change to continue to attract top talent. Diverse leaders are essential as champions of DEIB, for spearheading change, and as role models and mentors. DEIB efforts will not be successful unless led from the top. Failure to address the underrepresentation of marginalized groups in leadership may transmit unintended messages with a hidden curriculum of contradictory actions.⁷⁹

2.2.3. Eradicating Bias, Harassment, Structural Racism, and Structural Sexism, Including Sexual Harassment

1.	Microaggressions, bias, discrimination, and harassment are toxic to the cardiovascular community and must be intentionally eliminated by adopting the deliberate strategies and accountabilities in this document.
2.	The entire cardiovascular community is responsible for recognizing and being accountable for eliminating overt and subtle structural racism as vital to the mission and excellence of institutions.
3.	Excellence cannot be achieved without DEIB; therefore, the entire cardiovascular community is responsible and accountable for eliminating structural sexism and reducing and preventing sexual harassment by adopting deliberate strategies to ensure equity for all.

1. Microaggressions, bias, discrimination, and harassment are toxic to the cardiovascular community and must be intentionally eliminated by adopting the deliberate strategies and accountabilities in this document.

Rationale: In an ACC study of US cardiologists, 65% of women and 23% of men reported experiencing discrimination.⁷⁶ This and other actions are known to be highly detrimental, particularly to historically marginalized cardiovascular practitioners, including women and racially or ethnically underrepresented people.⁸⁰ Cardiovascular workplace and educational culture and climate must be assessed qualitatively and quantitatively and improved continuously with evidence-based, data-driven methods. Microaggressions, defined as commonplace verbal or behavioral slights or indignities that communicate hostile, derogatory, or negative attitudes, should be dealt with in the moment, which often requires training and practice. Macroaggressions, including bias, discrimination, and harassment, have multiple contributing factors and may benefit from root-cause analyses to identify and rectify the contributing systemic failings.⁷² Addressing harassment at academic societies and meetings is feasible⁸¹ and is particularly relevant to the ACC and AHA.

2. The entire cardiovascular community is responsible for recognizing and being accountable for eliminating overt and subtle structural racism as vital to the mission and excellence of institutions.

Rationale: While recognizing the adverse impact of interpersonal discrimination, it is as important to address historically rooted and culturally reinforced inequities that are

systematically maintained.⁸² Institutions must have specific, adequately resourced programs that examine all institutional structures and policies and procedures and rectify them to eliminate structural racism. These efforts must be accomplished in partnership with those who are URIM. The National Anti-Racism Coalition suggests that action in the following domains is required: conversation and naming of racism; education and learning from others' successes; liaison and partnerships (including at the community level); organizational self-examination and commitment to excellence; policy and legislation; and science and publications.⁵⁷

3. Excellence cannot be achieved without DEIB; therefore, the entire cardiovascular community is responsible and accountable for eliminating structural sexism and reducing and preventing sexual harassment by adopting deliberate strategies to ensure equity for all.

Rationale: Contemporary cardiology supports a sexist environment. Organizations and societies must protect individuals from and hold perpetrators accountable for gender and sexual harassment through confidential, easily accessible reporting followed by timely, transparent investigation. Sexual harassment must be regarded with the same seriousness as academic or scientific misconduct and treated accordingly. In particular, the ACC and AHA must restrict participation in committees, editorial boards, journal publications, and meetings as penalties for substantiated claims of sexual harassment. Further amendments to ethical codes should strengthen policies on bias, discrimination, and sexual harassment.

2.2.4. Achieving Equity, Inclusion, and Belonging: A Road Map

1.	Diversity metrics, including cardiovascular culture and climate, must be assessed and continuously improved to embrace best practices for team membership, citizenship, mutual respect, effective allyship, identifying personal privilege, relinquishing power, antiracism, antisexism, and supporting and promoting others.
2.	Trainings addressing individual, structural, and systemic racism, sexism, homophobia, classism, and ableism (prejudice against people with disabilities), with attention to proven techniques to reduce implicit bias, are essential to local and national DEIB efforts.
3.	Equity must be demonstrated through validated measures and with transparent reporting, including assessment of opportunity, mentorship, sponsorship, resource allocation, awards, promotion, compensation, and access to career flexibility, without compromising salary or advancement.
4.	Abuses of power in hierarchical and dependent relationships must be addressed by encouraging and destigmatizing the reporting of harassment, performing independent investigations, holding colleagues accountable, disseminating summaries of actions, and providing visible support to targets.
5.	The cardiovascular community must encourage, fund, conduct, and publish research evaluating programs and interventions to demonstrate and disseminate best practices in eliminating bias, harassment, racism and sexism, and advancing DEIB.

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1. Diversity metrics, including cardiovascular culture and climate, must be assessed and continuously improved to embrace best practices for team membership, citizenship, mutual respect, effective allyship, identifying personal privilege, relinquishing power, antiracism, antisexism, and supporting and promoting others.

Rationale: Institutions, professional societies, and organizations must collect, analyze, and report data on verifiable and reliable DEIB metrics to measure institutional progress. These metrics include workforce climate with respect to race, ethnicity, sex, sexual orientation, class, family status, religion, disability status, and other identities, with focused attention on intersectional identities (eg, Black women).⁷¹ An optimal workplace climate ensures that all individuals experience an equitable, respectful workplace with a sense of inclusion and belonging that is free of implicit and explicit biases.⁸³ The National Academies of Sciences, Engineering, and Medicine note that this is essential to improving retention and performance of individuals underrepresented in these fields.⁷¹

2. Trainings addressing individual, structural, and systemic racism, sexism, homophobia, classism, and ableism (prejudice against people with disabilities), with attention to proven techniques to reduce implicit bias, are essential to local and national DEIB efforts.

Rationale: Prospective studies have shown that implicit bias awareness and antiharassment trainings, combined with supportive policies and structures, result in a more equitable work climate (Table 3).^{66,81} Regular trainings must be implemented, with support for attendance time, and learnings acted on to limit the effects of individual bias on decision making. A recent National Academies of Sciences, Engineering, and Medicine report outlined effective interventions, including focusing on a growth (versus a fixed) mindset, active learning, promoting social connections, providing access to role models, allies, mentors, and sponsors, and highlighting the societal value of science, technology, engineering, and mathematics to improve climate and the recruitment and advancement of women, individuals who are URIM, and first-generation college students.^{71,84} The importance of implicit bias training is recognized by some states developing implicit bias training requirements for licensure of health professionals. Although training alone cannot fully address structural inequities such as sexism and racism, awareness of the problem and its negative impact on the community is an important first step.

3. Equity must be demonstrated through validated measures and with transparent reporting, including assessment of opportunity,

mentorship, sponsorship, resource allocation, awards, promotion, compensation, and access to career flexibility, without compromising salary or advancement.

Rationale: To identify and address systemic inequities experienced by women and those who are URIM, salient organizational and workplace metrics that go beyond simple numeric representation must be analyzed longitudinally and reported transparently (eg, DEIB dashboards).⁸⁵ Domains may include startup packages, access to resources, space, compensation, awards, speaker invitations, committee and editorial board membership, authorships, grant reviews, mentoring, sponsorship, advancement, promotion, and leadership positions. Vacancies in roles accompanied by titles or percentage effort for trainees, faculty, staff, or leadership must be announced openly and have clear, unbiased selection criteria; the selection outcomes must be diverse and inclusive by race, ethnicity, and sex.

4. Abuses of power in hierarchical and dependent relationships must be addressed by encouraging and destigmatizing the reporting of harassment, performing independent investigations, holding colleagues accountable, disseminating summaries of actions, and providing visible support to targets.

Rationale: Institutions, funding agencies, and professional meetings must have visible and enforced zero-tolerance policies on commitment to DEIB and offer targets of harassment confidential reporting mechanisms proscribing retaliation.^{86–88} After due process ensuring fairness to all parties, perpetrators of DEIB infractions must face consequences proportional to their violation and patterns of behavior, regardless of their stature. Restitution for targets' compromised careers must be provided. Institutions without formal strategies to actively encourage reporting, including protecting targets, will face the costs of a workplace that tolerates such behaviors, including lost productivity, recruitment costs, legal fees, and dysfunctional cultural environments.^{89,90}

5. The cardiovascular community must encourage, fund, conduct, and publish research evaluating programs and interventions to demonstrate and disseminate best practices in eliminating bias, harassment, racism and sexism, and advancing DEIB.

Rationale: Cardiology values evidence-based care; institutions and leaders must have the same relentless commitment to developing, validating, disseminating, and adopting evidence-based sustainable DEIB approaches, including policies, procedures, programs, and training. Discovering and disseminating multifaceted ways to efficiently and effectively eradicate bias, discrimination, and harassment will accelerate DEIB of the cardiovascular workforce. Sample areas of best practices research include, but are not

limited to, reporting, investigations, and public transparency of harassment; recruitment, retention, and advancement of those with intersectional identities; and efficacy of climate, allyship, and “upstander” interventions.^{89,90}

2.2.5. Coda

Diversity is the foundational concept that supports and permeates all recommendations in this section. Striving for diversity is an essential goal of individuals, leaders, educators, organizations, health systems, and professional societies. Diversity must inform not only what is believed and declared but also what is personally accepted and collectively accomplished. Limited progress over decades mandates action. DEIB must be cultivated within the cardiovascular field, whereas bias, structural racism, and sexism must be eradicated. The words of this section are firm and the goals are formidable, but the time for achievement is now. Actions, not platitudes, are needed. Failure is not an option, not only because it will deprive the profession of the richness and value that diversity brings to every facet of life but also because the goals of cardiovascular health cannot be achieved without it.

2.3. Task Force 3: Enhancing the Well-Being of Clinicians

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Professionalism in medicine has centered predominantly around the high standards of altruism that are to be upheld by clinicians.⁹¹ This higher calling has been well accepted in medicine, but it is increasingly recognized that clinician well-being is necessary to optimally meet patient needs. Clinician well-being is broadly defined as experiencing job satisfaction and engagement by being engaged with work, finding meaning in work, and having a sense of professional fulfillment (Figure 6). However, clinicians are currently facing unparalleled challenges that contribute to excessive stress, including consolidation of medical practices, higher productivity expectations, reduced reimbursements, legislative and regulatory requirements, explosion of electronic health records (EHRs), and the exponential growth of clerical burden. Furthermore, given the perplexing and shifting landscape in medicine, health systems and executives have focused largely on accomplishing the “Triple Aim” of improving

population health and enhancing the patient experience while reducing overall costs,⁹² which has placed additional burdens on physicians. The rapidly changing landscape in medicine, along with the demands of the healthcare environment, has had a negative effect on clinician well-being. The goals of health care must expand to the “Quadruple Aim” and now include clinician well-being because its absence can negatively affect the accomplishment of the patient-centered goals.⁹³

Burnout, one element of clinician distress detracting from clinician well-being, is classified as an occupational phenomenon, not as a medical condition, in the 11th Revision of the *International Classification of Diseases*. Burnout is defined as excessive levels of work-related emotional exhaustion, depersonalization, and dissatisfaction with personal accomplishments.⁹⁴ Burnout and reduced satisfaction with work-life integration are more prevalent in physicians compared with other US working adults.⁹⁵ In 2015, ≈27% of surveyed US cardiologists reported burnout, and 49% were stressed but not burned out. Overall, women and midcareer cardiologists reported burnout more frequently than men and early- or late-career cardiologists. Lack of control over workload, a hectic work environment, and insufficient documentation time were independently associated with higher rates of burnout.⁹⁶

Physician burnout has significant professional and personal ramifications. Studies have shown that burnout negatively influences patient care and is associated with higher rates of medical errors, lower quality of care, and decreased patient satisfaction. Physicians exhibit signs of burnout with increased disruptive behavior and loss of professionalism.^{97–101} Physician burnout can affect institutional costs through decreased productivity and poor job retention. In addition, these health system expenditures can be steep when taking into account the cost of replacing burned-out physicians.^{102–105} Burnout is also associated with negative personal life consequences, including higher rates of alcohol abuse, broken relationships, depression, and suicide.^{106–109} It is important to recognize that mental health conditions can occur across the spectrum of burnout. Many physicians who experience burnout will not develop mental health conditions; conversely, physicians might experience mental health conditions without burnout.

The high prevalence of physician burnout and its negative personal and professional effects notwithstanding, many health systems have been complacent and perhaps negligent in efforts to have an impact on burnout aside from promotion of individual-focused programs such as resilience and stress-management training. Furthermore, the lack of time to attend these programs is problematic, and many of them are targeted only to the most egregiously burned-out or disruptive physicians. Organizations also have focused much of their survey efforts on assessing employee engagement, often to the exclusion of physicians. Professional engagement

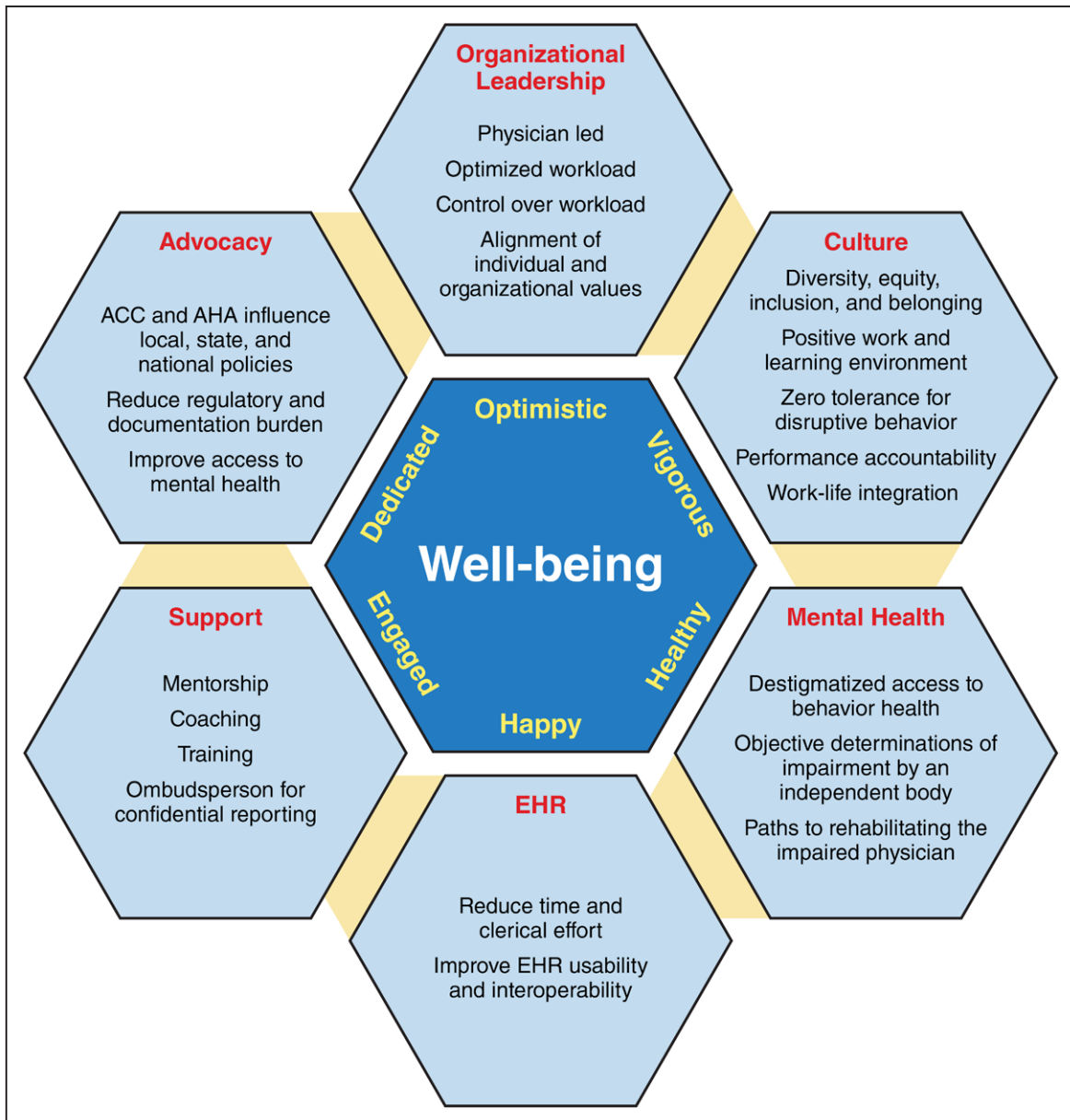


Figure 6. Elements of clinician well-being.

ACC indicates American College of Cardiology; AHA, American Heart Association; and EHR, electronic health record.

is described as vigor, dedication, and absorption. Seven key workplace drivers that can contribute to burnout, if less optimal, or engagement, if more optimal, include workload, efficiency, control over work, work-life integration, alignment of individual and organizational values, social support, community at work, and the degree of meaning derived from work.⁹⁹ The administrative burden of EHRs has clearly contributed to burnout among clinicians and is perceived to negatively affect in-office clinician-patient interactions and clinician satisfaction.¹¹⁰ Increased reporting requirements and demands for documentation for billing purposes and quality metrics generate clerical burdens that limit patient care time.¹¹¹ Much burnout is related to system issues and is best addressed from the perspective of organizational

approaches to improving the workplace.¹¹² The "Charter on Physician Well-Being" provides 4 key guiding principles: 1) Effective patient care promotes and requires physician well-being; 2) physician well-being is related to the well-being of all members of the healthcare team; 3) physician well-being is a quality marker; and 4) physician well-being is a shared responsibility.¹¹³ Furthermore, medical specialty societies need to support their members and provide recommendations to healthcare organizations and healthcare practices, as well as influence policy changes at the local, state, and national levels. The ACC and the AHA firmly believe that the well-being of clinicians and researchers and the entire healthcare workforce is paramount to providing excellent care to patients, their families, and society.

Separate from physicians who are burned out, but equally important to address, are those who exhibit disruptive behaviors or are impaired. The disruptive behaviors can vary from verbal threats, to refusal to cooperate with others or established protocols, and, more severely, to physical threats or throwing of objects. These disruptive behaviors can be intimidating and may negatively affect the workplace culture and compromise patient safety and quality.^{114,115} Impaired physicians are those who are incapable of satisfying their professional and personal responsibilities because of alcoholism, drug dependency, or psychiatric illness.¹¹⁶ Confidential identification of these individuals and supportive intervention plans are necessary.

This document provides recommendations for healthcare organizations and healthcare information technology developers and vendors to address well-being for clinicians, trainees, and researchers. It is important to note that the recommendations in the organizational strategies section are applicable not only for the well-being of clinicians and researchers in healthcare organizations but also for trainees in graduate and postgraduate training programs. Furthermore, the section on strategies for trainees and researchers provides specific tactics for addressing well-being, several of which can also be applied more broadly to all healthcare professionals. Additional recommendations are outlined to identify and assist physicians with impaired and disruptive behaviors. Although this document focuses on recommendations for clinicians in a broad sense and, in certain instances, specifically for physicians and researchers, we recognize that specific recommendations on well-being might be relevant for other types of healthcare professionals and researchers.

2.3.1. Organizational Strategies to Promote Well-Being

1.	Healthcare organizations must actively support and be accountable for the psychosocial health of their workforces.
2.	The majority of investment in clinician well-being research and interventions must be directed to improving organizational factors to create and sustain work environments within which clinicians thrive.
3.	Healthcare organizations must prioritize the regular assessment of clinician well-being as a marker of organizational health to evaluate implemented strategies and to identify areas of strength and ongoing opportunity.
4.	A key organizational strategy is to create an accountable professional well-being infrastructure, including the creation of a senior leadership position specifically dedicated to prioritizing clinician well-being.
5.	Healthcare organizations and medical specialty societies should participate in and lead advocacy initiatives to improve healthcare professional well-being, including attention to regulatory and documentation requirements and mental health support.

Efforts to promote clinician well-being and support thriving careers in medicine will require organizational infrastructure and adequate resources to maintain and sustain the strategic review, implementation, assessment, and monitoring of workplace programs. Senior leadership roles are necessary to ensure that clinician well-being concerns are integrated into organizational decisions and advocacy efforts at the highest levels and that solutions are supported within local work units. Although both individual and structural approaches promote well-being in the workplace, primary investment is needed to establish practice environments within which clinicians can optimally experience meaning from work, put their values into action, and feel purposeful in their daily activities. This investment should support the full range of approaches that promote clinician well-being, including leadership development at all levels, efforts to improve practice efficiency, building of a positive and inclusive culture of belonging, and providing an environment that allows individual strengths to flourish in collective efforts to achieve optimal healthcare system performance for patients.

1. Healthcare organizations must actively support and be accountable for the psychosocial health of their workforces.

Rationale: Medicine is an inherently challenging profession, and stress is inevitable. A resilient and healthy workforce is necessary to meet patients' needs, especially during peak periods of stress. Critical organizational functions to promote a resilient and healthy workforce include schedules that ensure adequate rest and recovery, support for individual physical and emotional health, and destigmatized confidential access to mental healthcare professionals.¹¹³ These are fundamental mechanisms to optimize physician performance. Clinicians generally possess high degrees of resilience, and resilience is necessary but not sufficient for well-being.¹¹⁷ Care should be taken to avoid shifting primary blame for distress onto clinicians. Healthcare organizations should assume a responsibility to provide work environments within which resilience, mindfulness, self-care, and other positive individual-focused skills and characteristics can be strengthened and sustained. For example, individualized professional coaching of physicians has been shown to reduce emotional exhaustion, improve quality of life, and build resilience.¹¹⁸

2. The majority of investment in clinician well-being research and interventions must be directed to improving organizational factors to create and sustain work environments within which clinicians thrive.

Rationale: Although both individual- and organization-focused approaches benefit workplace well-being,^{119,120} the primary drivers of occupational distress involve the environment within which these professionals work.^{99,121} These drivers include excessive workloads and inflexible schedules that increase work-home interference. Problematic

EHRs and other administrative demands, along with regulatory requirements that often increase clerical burden and distract attention from patients, also contribute to distress. Additional drivers include inefficient practice patterns and suboptimal team dynamics. Organizational solutions to address physician well-being should focus on 3 domains: practice efficiency, culture of wellness, and personal resilience.¹²² Solutions to reduce distress and promote well-being must prioritize meaningful, purpose-driven work on behalf of patients by improving the efficiency of practice and team-based interprofessional care.¹¹³

3. Healthcare organizations must prioritize the regular assessment of clinician well-being as a marker of organizational health to evaluate implemented strategies and to identify areas of strength and ongoing opportunity.

Rationale: Actions to promote clinician well-being should be informed and guided by data. This is analogous to assessing organizational performance in patient safety, quality, and other commonly tracked areas. Indeed, employee well-being should be considered a marker of quality for healthcare organizations to use in advancing systems-improvement initiatives.⁹⁹ Qualitative evidence can be derived from open discussions, group meetings, survey tools, and other means, often in combination. Providing safe spaces to share feedback openly can help organizations identify where needs are greatest and where solutions may already be active and can inform further efforts. Quantitative evidence can be obtained through the application of assessment metrics across a variety of well-being domains. Many instruments have robust validation data in support of their application to clinicians and have benchmark data allowing comparison with national norms.^{99,121} Regardless of the specific approach applied to obtain data, these efforts highlight how important well-being concerns are to organizational leadership and send a message to clinicians that their workplace cares about them.¹²³ Once the data are known, local and organizational groups can begin to work together to respond productively. Participation in national or regional research efforts and initiatives to identify gaps in research, to evaluate local interventions, and to develop a large regional or national database to improve the understanding of contributors and mitigators to physician burnout would be of additional benefit.

4. A key organizational strategy is to create an accountable professional well-being infrastructure, including the creation of a senior leadership position specifically dedicated to prioritizing clinician well-being.

Rationale: Successful efforts to promote clinician well-being require a secure infrastructure that establishes well-being as an organizational priority. A dedicated senior leadership position such as a chief wellness officer or similar role ensures that organizational leadership remains engaged in

well-being promotion and that decisions benefit the organization by incorporating the moral and financial value provided by a thriving healthcare workforce.¹²⁴ This role should be resourced to effect meaningful organizational change. The moral imperative to reduce clinician distress and increase well-being is clear, with important benefits to both clinicians and patients. This imperative is joined by a strong business case; distress among clinicians has been linked to lower productivity, greater likelihood of clinicians leaving their jobs, patient dissatisfaction, and reduced care quality, all of which cost healthcare organizations millions of dollars each year.^{103,125} The moral and financial benefits provide a robust return on investment for adequately resourcing the infrastructure and leadership roles necessary to ensure a positive impact on organizational processes and culture.

5. Healthcare organizations and medical specialty societies should participate in and lead advocacy initiatives to improve healthcare professional well-being, including attention to regulatory and documentation requirements and mental health support.

Rationale: Many of the threats to healthcare professional well-being involve clerical burdens, documentation requirements, and excessive administration burdens, often identified as necessary to satisfy external regulatory demands.^{99,121} Similarly, access to necessary mental health support is challenged by licensing requirements that may jeopardize healthcare professionals' careers when there is a history of treated mental health conditions, even when active impairment is not present.¹¹³ Addressing these issues requires advocacy efforts by healthcare organizations and medical specialty societies to influence policies and regulations that will destigmatize mental health care and better support healthcare professional well-being as a key driver of excellence in patient care.¹¹³ Effective advocacy should occur at the individual, organizational, and national levels and in partnership with regulatory and legislative bodies.

2.3.2. Addressing Well-Being Among Trainees and Researchers

1.	Postgraduate training programs must perform self-assessments of the curriculum and schedule, with trainee input, and ensure that subject areas of personal well-being, leadership, and emotional intelligence are included.
2.	Institutions with graduate and postgraduate training programs must make both preventive and responsive mental health resources available.
3.	Postgraduate training programs must develop a confidential ombudsperson program that will allow confidential reporting of any mistreatment and access to institutional resources for support and restitution.
4.	Trainees and researchers should receive formal training in process improvement science.
5.	Postgraduate training programs should have formalized mentorship arrangements in place for trainees and researchers, including periodic review of the learner's experience of the quality of the professional relationship.

The academic community must prioritize the well-being of our trainees and researchers. *Trainees* refers to medical students, residents, fellows-in-training, graduate students, and postgraduate students. This group represents an at-risk population because of their place within the structure of institutions. Evidence shows that trainees who show signs of burnout, anxiety, and depression during their training remain at higher risk of these maladies as they progress through their careers.¹²⁶ The false idea has been propagated that work is depleting, with life outside of work as its only antidote—the work-life balance proposition. In truth, it is imperative that we find harmony between our work lives and our lives outside of work because the nature of medicine and research will always be time demanding. This will require attention to the development of personal mental and behavioral health skills, ongoing stakeholder advocacy, and a focus on current healthcare landscape work environments. Our ability to provide nurturing support and tools to help trainees redesign the multitude of intrinsic work factor complexities that lead to workplace burnout is paramount. These recommendations, taken in sum, address the fact that burnout is not a one-size-fits-all problem. Indeed, burnout has its roots in both “role strain” and “role conflict.”¹²⁷

1. Postgraduate training programs must perform self-assessments of the curriculum and schedule, with trainee input, and ensure that subject areas of personal well-being, leadership, and emotional intelligence are included.

Rationale: Most attempts to mitigate burnout, including duty hour reduction, have shown only small to modest decreases in its prevalence and leave a large group of trainees struggling with these issues. This is caused, in part, by the fact that trainees experience different types of burnout and therefore have differing paths to both recovery and prevention. One dichotomous path in that journey is predicated on whether the burnout is existential (loss of meaning in medicine and an uncertain professional role) versus circumstantial (self-limited circumstances and environmental triggers).¹²⁸ In addition, in understanding that systemic issues lead to program well-being problems, the systemic issues should be holistically reviewed in the context of programmatic structure, including such elements as call schedules and order of rotation assignments, to allow development of professional autonomy. Regularly scheduled didactic sessions, small-group discussions, self-care and leadership portfolios focusing on emotional intelligence, communications, and team-building skills can help build an educational culture of wellness.¹²⁹

2. Institutions with graduate and postgraduate training programs must make both preventive and responsive mental health resources available.

Rationale: Physicians who experience mental health issues and burnout are less likely to seek treatment.¹³⁰ Commonly

cited barriers to physicians seeking help include time constraints, treatment costs, concerns about confidentiality, perceived stigma, and concerns about problems with obtaining a license or hospital privileges.¹³¹ Although these issues are not unique to trainees, it is reasonable for postgraduate training programs to consider an autoenrollment process to mental health resources for their trainees on a scheduled basis. Offering residents regularly scheduled well-being assessments with protected time off from other duties is one method to mitigate barriers that prevent residents from using counseling resources.¹³² To convey normalcy and to reduce the stigma associated with seeking care, the strategy could be made “opt-out.”¹³³

3. Postgraduate training programs must develop a confidential ombudsperson program that will allow confidential reporting of any mistreatment and access to institutional resources for support and restitution.

Rationale: Despite implemented reforms in the 1990s, more than one-half of all medical trainees still indicate that they have been intimidated or physically or verbally harassed.¹³⁴ Although program directors are important resources for trainees and researchers facing mistreatment, it is vitally important that learners have the resource of a neutral, confidential, and informal complaint-handling service from someone who is not formally part of the program structure and a clear resolution mechanism that protects the trainee and researcher. The program can make this available either individually or as part of a broader institutional effort.

4. Trainees and researchers should receive formal training in process improvement science.

Rationale: Because the genesis of burnout is related, in part, to the nonclinical administrative duties required in health care and research, it is imperative that trainees have some basic understanding of change science and healthcare delivery science. By having these tools, trainees can actively participate in bringing changes to workflows and processes that improve the work environment and patient care. Trainees tend to have a much closer view of the problems noted on the front lines and are thus ultimately advantaged to help to create solutions to improve the work environment. Many institutions have taken this a step further to create Housestaff Quality Councils with sponsorship from the highest levels of the organization.¹³⁵

5. Postgraduate training programs should have formalized mentorship arrangements in place for trainees and researchers, including periodic review of the learner’s experience of the quality of the professional relationship.

Rationale: Mentorship improves personal development, research productivity, and career satisfaction.^{136,137} Mentee participation in the pairing process and direction of

the relationship are critical components of a successful and rewarding experience.¹³⁸ Facilitated selection of formal mentors, mentee investment in the matching process, and brief training initiatives lead to increased high-quality mentoring relationships.¹³⁹ Therefore, a well-thought-out and well-planned mentorship program can help facilitate individual and career growth.

2.3.3. Well-Being Strategies Focused on Health

1.	HIT developers and vendors must collaborate with clinicians, researchers, and other vendors to improve EHR usability and interoperability.
2.	HIT developers, healthcare organizations, and employers must work to improve practice efficiency and to reduce the time and clerical effort that clinicians spend on EHR documentation.

Information Technology

HITs were initially intended to support clinicians in providing high-quality and efficient patient care; however, clinicians frequently report these technologies to be time-consuming, duplicative, and barriers to meaningful patient care and interaction. Collaborative strategies are necessary to engage clinicians to work with HIT developers and healthcare organizations to develop HITs that not only improve patient outcomes but also improve clinician experience. Involvement of these key stakeholders in improving the usability of HIT can reduce clinician burden while optimizing clinical workflow, improving clinical decision-making tools, and reducing the clerical burden. The lack of EHR interoperability limits access to necessary patient information in a timely fashion, which has further exacerbated clinician concerns about the transition to the EHR. Furthermore, improved HIT and reduced clerical burdens would allow clinicians to focus more of their efforts directly on their patients.

1. HIT developers and vendors must collaborate with clinicians, researchers, and other vendors to improve EHR usability and interoperability.

Rationale: Well-designed EHR features that take into account clinical workflow can assist in improving clinical efficiency and quality outcomes. They can also facilitate better communication between clinicians and optimize clinician-patient interactions. However, poor EHR usability can contribute to increased clinician burden and poor clinical workflows. There is wide variability in task completion times, number of clicks, and error rates among clinicians completing basic EHR functions.¹⁴⁰ EHR usability issues such as system feedback and visual display can result in the incorrect prescription of medications or doses, resulting in potential patient harm.¹⁴¹ A key obstacle to addressing HIT usability has been the prohibition of communication with other clinicians, researchers, healthcare organizations, and HIT developers about these usability

challenges because of “gag clauses” written into contracts by EHR vendors. Evaluations for possible systems or upgrade purchases should include formal assessments of usability and the impact on clinician workload. Furthermore, interoperability among different EHR vendors or similar vendors in different health systems is also a major impediment to care and contributes to increased administrative burden on clinical staff.¹⁴²

2. HIT developers, healthcare organizations, and employers must work to improve practice efficiency and to reduce the time and clerical effort that clinicians spend on EHR documentation.

Rationale: Studies have shown that clinicians spend a significant amount of their work hours interacting with EHRs.^{143,144} Moreover, physicians spend an additional 1 to 2 hours on EHRs at work for every 1 hour spent on face-to-face interaction with patients in the office, and they spend an additional 1 to 2 hours of their personal evening time working on EHRs or other clerical work.¹⁴⁴ Insufficient time for EHR documentation has been associated with an almost 3-fold increase in the odds of burnout in clinicians, whereas those who report excessive time documenting at home have almost double the odds of burnout.¹⁴⁵ Redesigning clinical workflow and the process of documentation such as the addition of nonclinical scribes may improve clinical workflow and increase both clinician and patient satisfaction.^{146–148} Technical solutions, for example, badge-scan log-in rather than manual entry of user name and passwords and voice recognition software that allows dictation rather than typing, also can improve workflow by reducing the number of keystrokes, improving efficiency, and reducing computer screen time.¹²¹ HIT developers and healthcare organizations should optimize EHR functionality to improve EHR efficiency while reducing clerical burden and improving clinician satisfaction. Likewise, advances in technology with artificial intelligence may accelerate meaningful digital transformation in medicine.

2.3.4. Identifying Symptoms of the Disruptive Physician

1.	Healthcare systems must develop educational programs designed to make physicians aware of what constitutes disruptive behavior and their responsibility to be professional and respectful team members at all times.
2.	Healthcare systems must develop policies and procedures to include a code of behavior and disruptive behavior policies, confidential reporting systems, compliance enforcement, and follow-up and feedback.
3.	Healthcare systems must establish physician well-being programs focused on areas such as stress management, awareness, and resilience training for both prevention and intervention.
4.	Physicians should be “upstanders,” not bystanders, to disruptive behavior.

Table 4. Signs and Symptoms of Disruptive Physician Behavior

Physical signs	Aberrant symptoms
Irritability	Use of profanity
Fatigue	Name calling
Changes in weight	Sexual comments
Observed heavy drinking or drug use	Racial and ethnic jokes
Disheveled appearance	Outbursts of anger
Slurred or pressured speech	Intimidation
Disorganization and poor attention	Nonadherence
	Criticizing or undermining other members of the healthcare team
	Frequent absences or tardiness
	Avoidance of peers or superiors
	Unusual work hours

Disruptive behavior is defined by the AMA Code of Ethics as “any abusive conduct, including sexual or other forms of harassment, or forms of verbal or nonverbal conduct that harms or intimidates others to the extent that quality of care or patient safety could be compromised.”⁸ Disruptive physician behavior can range from minor profanity to outright assault^{114,149} and can be habitual or isolated (Table 4). Disruptive physician behavior has a substantial negative impact on patient care and an adverse effect on the morale of members of the medical team. There is an urgent need to identify disruptive behaviors, to understand what contributes to, triggers, or provokes disruptive behaviors, and therefore to establish strategies for corrective action, educational and training programs, rehabilitation, and monitoring for the disruptive physician.^{115,149}

1. Healthcare systems must develop educational programs designed to make physicians aware of what constitutes disruptive behavior and their responsibility to be professional and respectful team members at all times.

Rationale: With the expanding demands on individual physicians for the practice of medicine and healthcare delivery, disruptive physician behavior occurs at a higher frequency and is a serious problem.¹¹⁴ A report from 2006 estimated that 3% to 5% of physicians had demonstrated behavior that interfered with patient care or could be expected to interfere with the process of delivering quality care.¹¹⁴ Comprehensive educational programs should be provided to include the definitions of professional behavior, the importance of diversity, equity, and inclusion, personality profiling (behavioral profiling or personality testing), stress management techniques, and anger management training. Programs should be established to train physicians in team dynamics and to create an organizational inclusive culture that values team

behavior. Specific educational programs and training workshops on communication skills and team collaboration should be implemented.

2. Healthcare systems must develop policies and procedures to include a code of behavior and disruptive behavior policies, confidential reporting systems, compliance enforcement, and follow-up and feedback.

Rationale: Important factors in creating a culture of dignity and respect for the entire medical team include the development of policies and procedures and the establishment of an effective reporting system for disruptive and unprofessional behavior. To guarantee consistency, many healthcare systems have formed dedicated nurse-physician-staff relations committees. The committee’s responsibilities can include education and staff training and the coordination of appropriate follow-up on reported unprofessional events. A culture of ongoing evaluations of unprofessional events and the establishment of policies related to the code of conduct and mechanisms for problem resolution reinforce a leadership commitment to professional behavior and communicate to the medical team the expected professional behaviors, which should be role-modeled by physician leaders.^{115,149}

3. Healthcare systems must establish physician well-being programs focused on areas such as stress management, awareness, and resilience training for both prevention and intervention.

Rationale: Factors that contribute to the development of disruptive behavior by physicians can be characterized as internal or external.^{149,150} Internal factors that affect physicians’ behavior include age, generational issues, sex, sexual orientation, culture, race, ethnicity, spirituality, geography, life experiences, mood, and personality.¹⁴⁹ The stresses of training, the rigid healthcare hierarchy, healthcare reform, work-related stress, burnout, the work environment, adverse events, litigation, and personal issues are a few of the contributing external factors that can adversely affect physicians’ well-being and behavior. Suggestions for creating a culture of well-being include creating positive work and learning environments, reducing physician administrative burden, and providing support to physicians for improved mental, emotional, and physical well-being.^{151,152}

4. Physicians should be “upstanders,” not bystanders, to disruptive behavior.

Rationale: All physicians should actively engage in maintaining a culture of dignity and respect. It is the responsibility of physicians to address and report statements or actions that threaten professionalism in the workplace.

2.3.5. Identifying and Assisting the Impaired Clinician

1.	Clinicians and team members must be taught to recognize a potentially impaired physician and to understand the process for confidential reporting of concerns.
2.	Each care setting must develop an intervention plan to handle reports of an impaired clinician.
3.	Objective measures must be used to establish physician impairment.
4.	Programs should be created and be accessible to treat and rehabilitate impaired physicians and, when appropriate, to enable their safe reentry into practice.

In 1973, the AMA defined the impaired physician as one who is unable to fulfill professional and personal responsibilities because of psychiatric illness, alcoholism, or drug dependency.¹¹⁶ The prevalence of clinicians impaired by alcohol or drug abuse is estimated at 2% to 14%.¹⁵³ It is more challenging to quantify the prevalence of depression among physicians. Risk factors for substance abuse include a mood disorder or a family history of substance abuse. Work-related stress exacerbates symptoms of depression and anxiety. Alcohol is the most commonly abused substance among physicians, but access to prescriptions and medications can result in drug abuse, particularly involving benzodiazepines and opioids. Impaired physicians usually function adequately for years until the problem becomes more advanced and interferes with clinical practice. More recently, the definition of impairment has been broadened to include cognitive dysfunction, which may be secondary to certain medical conditions or to advancing age.

1. Clinicians and team members must be taught to recognize a potentially impaired physician and to understand the process for confidential reporting of concerns.

Rationale: Physicians are at high risk for psychiatric issues, particularly depression and substance abuse. Alcohol and drug use is often an attempt to self-medicate and to reduce stress. Physician impairment can be a consequence of a psychiatric, substance abuse, physical, or cognitive disorder. The impaired physician often experiences personal difficulties before professional performance becomes affected.¹⁵³ Changes in mood or behavior, low productivity, and decreased concentration may become noticed in the workplace (Table 4). Overt intoxication may be observed at social gatherings or in the workplace.

2. Each care setting must develop an intervention plan to handle reports of an impaired clinician.

Rationale: Ideally, the impaired physician or his or her family and friends will address the problem before it manifested in the clinical realm. However, it is not unusual for colleagues or supervisors to raise concerns

based on observed behavior. This should lead to a discussion by a knowledgeable team led by individuals trained in interventions. The content of the discussion should be highly confidential, objective, and fact based.¹⁵⁴ If the physician is receptive to intervention, referral to a physician health program is recommended.

3. Objective measures must be used to establish physician impairment.

Rationale: Physicians are extremely vulnerable to allegations of mental health or substance abuse disorders. Repercussions could include stigmatization, loss of income, and possible litigation. Therefore, it is imperative that institutional leaders follow a standardized protocol and confidentially perform an exhaustive investigation of each case. Because physicians are usually obliged to pay for forensic psychiatric evaluation and residential rehabilitation programs, they should not be imposed frivolously. Concerns have been raised about the objectivity and potential COIs of some physician health programs, and these issues require greater scrutiny.¹⁵⁵ Physician help programs should allow an appeals process and should eliminate financial incentives to mandate treatment.

4. Programs should be created and be accessible to treat and rehabilitate impaired physicians and, when appropriate, to enable their safe reentry into practice.

Rationale: Physician health programs offer confidential treatment and assistance to impaired clinicians. They may be independent or administered by state licensing boards or state medical societies. It is important to separate support from disciplinary action. Clinicians resistant to supportive intervention may be faced with more punitive measures to protect patient safety.

2.3.6. Additional Considerations and Caveats

Numerous laws, policies, regulations, and standards set for health care in the United States contribute to the administrative burden placed on clinicians, including clinical documentation, measuring and reporting quality metrics, prior authorization forms, licensure requirements, and board certification. As a result, very specific documentation criteria for drug and procedural reimbursement have resulted in boilerplate text, templates, and tables that increase time for physician documentation for billing purposes but add limited clinical value. Healthcare policy makers, regulatory bodies, and accreditation groups should identify, reduce, or eliminate policies, rules, and administrative processes that provide minimal or no value to patient care, increase unnecessary administrative burden, and negatively affect physician well-being.

The stigma of seeking mental health help in the United States is highly prevalent, is especially pervasive in medicine, and is associated with barriers to seeking

help because of cultural, perceptual, healthcare organizational, and licensing board issues. Robust efforts are needed to reverse this, including reforms of questions asked by licensing boards, employers, and credentialing boards. Furthermore, legislative reforms that legally protect clinicians who seek help for mental health conditions are necessary such that their personal health information is not admissible in medical malpractice litigation cases.

2.4. Task Force 4: Patient Autonomy, Privacy, and Social Justice in Health Care

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Into whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrong-doing and harm...and whatsoever I shall see or hear... if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets.

— Hippocratic Oath¹⁵⁶

From the Hippocratic Oath,¹⁵⁶ the first known formal ethical statement in Western medicine, through the landmark Belmont Report of 1979,¹⁵⁷ key biomedical principles that govern medical practice and research have been codified and emphasize the primacy of the principles of respect for individuals, beneficence, and justice. This section of the 2020 Consensus Conference focuses on 3 specific areas relevant to contemporary biomedicine: 1) patient autonomy, particularly as it relates to clinical decision making; 2) privacy, data access, and transparency with the expansion of research and proliferation of electronic biomedical data resources; and 3) social justice in medical education and clinical practice.

2.4.1. Patient Autonomy

Respect for patients requires an acknowledgment of their autonomy and of the importance of the alignment of their care with their goals and values. Historically, the balance between paternalism and autonomy in medicine has evolved. In an acknowledgment of the importance of patient autonomy, informed consent has emerged as an ethically and legally required component of care before the performance of diagnostic or therapeutic procedures involving meaningful risk. However,

because it does not explicitly consider how individual values might influence decisions, informed consent, although necessary, is insufficient to ensure the exercise of patient autonomy.

The NAM acknowledges this nuance in its definition of patient-centered care, which it characterizes as “care that is respectful of, and responsive to, individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.”¹⁵⁸ Thus defined, patient-centered care is grounded in the ethical principle of autonomy and has a sound basis in legal, moral, and human rights theories.¹⁵⁹ Shared decision making (SDM) is defined by the National Quality Forum as “a process of communication in which clinicians and patients work together to make informed healthcare decisions that align with what matters most to patients and their individual concerns, preferences, goals, and values.”¹⁶⁰ Thus, SDM is a structured process that involves both patients and clinicians to generate decisions tailored to both the best available evidence and articulated patient preferences. Patient goals and values can be elicited to support patient-centered decision making; in cases of relatively high-stakes decisions, formal SDM is used to ensure the delivery of care that is optimally aligned with the patient’s objectives.

2.4.2. Data Privacy, Transparency, and Access

The principle of respect for individuals supports the provision of complete and accurate information about research studies to participants throughout the conduct of the study and the obligation to disseminate the results of research in the interests of the public good. Investigators have the responsibility to clearly communicate the objectives of biomedical research to potential study subjects in the consent process and to inform those enrolled in studies of the research results. Ideally, investigators would declare their objectives in a public forum before the conduct of research to mitigate the temptation to publish only those findings that are aligned with the interests of the research sponsor or the investigators themselves. As a corollary, the dissemination of research results, regardless of the findings, acknowledges the contributions of participants to generalizable knowledge.

In the electronic age, healthcare data have proliferated exponentially. EHRs have the capacity to expand patients’ access to their own information. However, substantial barriers to such access exist, undermining patient engagement and education. Furthermore, although electronic platforms have facilitated clinical care, the vast data that they generate, coupled with the potential value of these data, create new challenges to patient privacy. Organizations providing health care share patient information with external partners for reasons not limited to improving clinical care, typically without patient knowledge and

sometimes in the context of exclusive agreements intended to generate profit.

2.4.3. Social Justice

Social justice is the belief in and commitment to the realization of access to quality health for all. The principles of respect for individuals and justice require that clinicians and the systems in which they work provide high-quality care to all patients, regardless of any underlying characteristics. Complicating this is the reality that as much as 80% of a person's health is determined by the social and economic conditions of their environment. These are called the social determinants of health. The World Health Organization asserts that the "social conditions in which people are born, live and work are the single most important determinants of good or ill health, of a long and productive life, or a short and miserable one."¹⁶¹ Inequities in health care and outcomes are a function of where individuals live (urban, suburban, or rural). A recent AHA presidential advisory on rural health noted that "rural areas have higher death rates for cardiovascular disease and stroke than urban areas, and gaps are widening."¹⁶² Identifying mechanisms to address growing rural-urban disparities is seminal to the development of effective health policy.

Allyship is defined as "the practice whereby a person or group in a privileged position seeks to operate with a marginalized person or group."^{162a} Allyship plays an important role in patient care and addressing systematic inequities. Overcoming health disparities and achieving health equity are also dependent on the cultural competence of the healthcare clinician: the ability to meet people where they are, which requires knowing who they are. To achieve social justice and health equity, we must go to the margins. To center in the margins is to shift the discussion from the perspective of the majority group to that of the marginalized group.¹⁶³

Cardiovascular clinicians and organizations must strive to support every person to attain their full health potential and to ensure that no one is disadvantaged from achieving their potential because of race, sex, sexual orientation, disability, gender identity, education, social position, or other personal or socially determined circumstances. Recent events highlight the continued struggles in this country with racism. It is increasingly acknowledged that race is not a biological construct but rather a sociopolitical designation based principally on physical features.¹⁶⁴ Racism "is a system of structuring opportunity and assigning value based on the social interpretation of how one looks (which is what we call "race") that: unfairly disadvantages some individuals and communities; unfairly advantages other individuals and communities; and saps the strength of the whole society through the waste of human resources."⁵⁷ Neither race nor racism is biological. Racism, not race, is at the core of health disparities. Thus, racism is a public health crisis.

2.4.4. Recommendations: Patient Autonomy

1.	Medical care should be patient-centered, meaning it should be tailored to optimize the outcomes and to support the values most important to the individual.
2.	Clinicians should elicit and document preferences and values important to the patient, including the outcomes most important to them.
3.	Although the principles of patient-centered care apply broadly, formal SDM should be reserved for decisions with significant tradeoffs among reasonable options.
4.	Tools designed to support formal SDM should be designed with multistakeholder input, including both clinicians and patients.
5.	Payers and healthcare systems must support policies and infrastructure that facilitate patient-centered care, including formal SDM when appropriate.

1. Medical care should be patient-centered, meaning it should be tailored to optimize the outcomes and to support the values most important to the individual.

Rationale: Patient-centered care is growing in both practical and political importance. The NAM defines patient-centered care as "providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions."¹⁵⁸ Grounded in the ethical principle of autonomy, it has a sound basis in legal, moral, and human rights theories.

Optimizing outcomes important to the patient requires in-depth discussions about health values and priorities. Providing patient-centered care may be relatively easy when the patient and doctor agree on the desired outcomes. However, it becomes increasingly difficult when a patient desires an outcome discordant from what "good" medical evidence suggests. For example, a patient may decline an implantable cardioverter-defibrillator despite having a high risk for sudden cardiac death.¹⁶⁵ Some patients may decline an implantable cardioverter-defibrillator because they do not believe they are in a high-risk group or they do not trust the clinician. In these cases, ensuring that the patients are fully informed is the appropriate requisite toward achieving patient-centered care. Another patient may choose to forgo an implantable cardioverter-defibrillator because they do not want a procedure because their goal is not longevity; they do not want to get shocked and do not see sudden cardiac death (dying quickly or in their sleep) as the worst possible outcome.¹⁶⁶ In this case, the patient-centered approach would support the patient's decision to decline the therapy.

Patient-centered care requires methods to measure and optimize patient-reported outcomes. Strategies to determine the concordance between care provided and the patient's goals are of paramount importance. Recommendations based on clinical information alone may be highly influential to patients' choices. However,

Table 5. Definitions of Values, Goals, and Preferences

Construct	Definition
Values	Values are a set of fundamental beliefs about one's self and life that are stable over time despite changing circumstances.
Goals	Goals in health care are the desired outcomes (objects, aims, health states) of a particular healthcare service or procedure and can be expressed along multiple dimensions.
Preferences	A person's overall most-favored option within a discrete set of effective treatment options relating to a single medical condition.

patient-centered recommendations should be based on an understanding of both the clinical information and the outcomes that matter most to the patient rather than just the clinical information alone.¹⁶⁷ Finally, patient-centeredness is a largely Western construct; many other cultures make decisions differently. Imposing a patient-centered approach without fully exploring the cultural values and norms may not be helpful and could be harmful.¹⁶⁸

2. Clinicians should elicit and document preferences and values important to the patient, including the outcomes most important to them.

Rationale: Although guidelines identify clinically appropriate therapies, they cannot address individual issues that may influence the ultimate decision to receive a treatment. An important aspect of patient-centered care is exploring what is important to patients. At its core, this recommendation is about communication; a particular challenge is that defining values, goals, and preferences can be confusing. For the purpose of this discussion, values are core beliefs that are more stable and drive the goals and preferences, goals are the outcomes that a person hopes to achieve, and preferences are the choices that are ultimately made (Table 5).¹⁶⁹ It is also important to document these recommendations so that other members of the medical team are aware of the goals most important to the patient. Ultimately, achieving this recommendation requires skill in discovering the patients' values, goals, and preferences.

3. Although the principles of patient-centered care apply broadly, formal SDM should be reserved for decisions with significant tradeoffs among reasonable options.

Rationale: SDM is a formal process of involving patients directly in their care. The National Quality Forum defines SDM as "a process of communication in which clinicians and patients work together to make informed healthcare decisions that align with what matters most to patients and their individual concerns, preferences, goals, and values."¹⁶⁰ Beyond presenting information to patients and asking them to choose their therapy, SDM is a structured process between patients and clinicians whereby treatment recommendations are tailored to

both the best evidence and well-informed patient preferences. SDM is an ideal that applies broadly to many aspects of medicine, and the communication skills necessary to achieve SDM such as responding to emotion and managing uncertainty apply broadly across many medical decisions.¹⁷⁰

Recently, CMS has included requirements for SDM in national coverage decisions. Although this has incentivized implementing SDM in practice, these recommendations have been met with significant resistance, in part because the mandate is "unfunded" and is perceived as a mechanism of achieving cost containment.¹⁷¹ Although the principles of formal SDM apply broadly to many medical decisions, formal SDM using decision aids, a decision coach, or the multidisciplinary team should be reserved for big decisions with significant tradeoffs among the options. CMS would do well to provide a list of decisions for which formal SDM may be necessary.¹⁷²

4. Tools designed to support formal SDM should be designed with multistakeholder input, including both clinicians and patients.

Rationale: Patient decision aids are evidence-based tools designed to support SDM between a clinician and a patient, not replace it. The evidence base for rigorous decision aids is robust, including numerous trials demonstrating that patient decision aids improve knowledge, satisfaction, and patient and clinician communication; increase patient involvement in decision making; and reduce patient decisional conflict and regret.¹⁷³ Patient decision aids come in many forms, including paper, video, interactive websites, and even telenovelas. Nevertheless, patient decision aids are rarely implemented; much work remains in both the design and implementation of these tools to integrate them into clinical workflow.¹⁷⁴ Decision aids must be designed rigorously, built on a solid theoretical foundation, and then modified according to both patient and clinician input. The clinician's perspective is particularly important to facilitate clinical implementation. The International Patient Decision Aid Standards provide useful guidelines on which decision aids should be based.¹⁷⁵

5. Payers and healthcare systems must support policies and infrastructure that facilitate patient-centered care, including formal SDM when appropriate.

Rationale: The most important barriers to the implementation of SDM in practice include time and expertise. Expecting clinicians alone to bear the burden of achieving patient-centered care in dynamic clinical settings is unrealistic. Although patient-centered care is an ideal, many barriers can be overcome, including creating space for clinicians and the clinical team to have the time and skills to enact the recommendations provided in the preceding text, particularly when formal SDM is appropriate. Clinicians frequently cite time as the

primary barrier to participation in SDM.¹⁷⁶ Payers must acknowledge the time required to achieve patient-centered care—particularly formal SDM—in their payment policies. Healthcare systems must create structures of care to facilitate patient-centered care; in addition to providing clinicians with adequate time, innovations such as group visits and telehealth may be helpful in this respect.

2.4.5. Recommendations: Data Privacy, Transparency, and Access

1.	Researchers should commit to prospective registration of their protocols and reporting results in a public registry such as ClinicalTrials.gov, publishing results in the peer-reviewed medical literature, and sharing patient-level data (with consent and protection of confidentiality) within a reasonable period of time after completion of a study. In addition, research funders should require these practices as a condition of funding.
2.	Investigators conducting clinical trials and other prospective research should report aggregate research results and, in appropriate circumstances, individually specific study findings in plain language summaries to research participants.
3.	Patients should have access to medical information collected and aggregated about them with minimal financial and nonfinancial barriers.
4.	Researchers, hospitals, and health systems engaging in medical information sharing, including from EHRs, should consider using a Data Governance Board that is patient elected and includes at least 1 patient representative to adjudicate access requests and sharing of medical data.
5.	Hospitals and health systems should generally avoid exclusive licensing of their data sets for research because this can limit their use for advancing public health goals.

1. Researchers should commit to prospective registration of their protocols and reporting results in a public registry such as ClinicalTrials.gov, publishing results in the peer-reviewed medical literature, and sharing patient-level data (with consent and protection of confidentiality) within a reasonable period of time after completion of a study. In addition, research funders should require these practices as a condition of funding.

Rationale: Trial registration involves investigators pre-specifying how a trial will be conducted, including the number of participants to be enrolled, primary and secondary outcome measures, and eligibility criteria, allowing peers to better evaluate a study once complete and mitigating misreporting of outcomes.

Results reporting involves publicly documenting in a registry the basic results of a trial such as primary and secondary outcome values and adverse events. Reporting results and publication each ensure that the information learned through a trial is disseminated to clinical and scientific communities. It is essential to quality

medical evidence and patient care involving drug therapy. Furthermore, dissemination is integral to honoring and protecting research participants because medical experimentation on humans is ethically justified largely by its potential to contribute to generalizable knowledge.^{177,178} Moreover, many patients and other people volunteer for trials out of altruism, to help others, which can be hard to do if trial results and data remain hidden. Most are willing and interested in having these data shared.¹⁷⁹ Furthermore, trial dissemination and data sharing support innovation by allowing scientists to build on knowledge from prior research and to avoid unnecessary duplicative research, costs, and risks to participants.^{180–182}

2. Investigators conducting clinical trials and other prospective research should report aggregate research results and, in appropriate circumstances, individually specific study findings in plain language summaries to research participants.

Rationale: Sharing summaries of research results with research participants honors and respects their contributions to the research process, improves the transparency around trials, and can help build and improve trust in research.^{38,183} Most research participants expect to receive the results of the trials in which they participate; however, this rarely occurs.^{184,185} Moreover, most (68%) research participants will not participate in additional future research if they do not receive the results of the studies in which they participated.¹⁸⁶ The National Academies of Sciences, Engineering, and Medicine recommend returning not only aggregate summary results but also individually specific study findings to patients in certain circumstances, with the “justification for returning results becoming stronger as both the potential value of the result to participants and the feasibility of return increase.”¹⁸⁷ One survey found that an overwhelming majority (90%) of patients wanted access to personally relevant clinical study findings, responding “the more we know, the better decisions we can make for ourselves.”^{185,188}

3. Patients should have access to medical information collected and aggregated about them with minimal financial and nonfinancial barriers.

Rationale: In the United States, the Health Insurance Portability and Accountability Act gives patients the right to receive a copy of health data collected about them by entities protected by the act—generally covering EHRs, and radiology, pharmacy, and laboratory systems data—within 30 days of request. The Health Information Technology for Economic and Clinical Health Act and 21st Century Cures Act further strengthen this right. Unfortunately, this right is neither well monitored nor enforced, and EHR data can be hard and sometimes costly to access.^{189–191}

4. Researchers, hospitals, and health systems engaging in medical information sharing, including from EHRs, should consider using a Data Governance Board that is patient elected and includes at least 1 patient representative to adjudicate access requests and sharing of medical data.

Rationale: The Health Insurance Portability and Accountability Act generally does not require consent for many forms of medical information sharing, including from an individual's EHR. Personally identifiable data can be shared with the health systems' business partner for patient care purposes. Deidentified medical data can be shared for most any purpose, with most any third party, without explicit patient consent.¹⁹² A rationale for bypassing consent was that deidentification could sufficiently protect people's privacy. Today, in contrast to when the Health Insurance Portability and Accountability Act was enacted, deidentified data can be more easily reidentified, given vast amounts of public data about people and abilities to link multiple data sets, with certain populations at greater risk of reidentification than others (such as patients with rare diseases).^{193,194} As a result, the role of consent in medical data sharing, including deidentified data, is being questioned.

Some experts advocate a dynamic consent model, empowering each patient to exercise consent for every secondary data use or to consent to categories of secondary uses or users of their data.^{195–197} This approach is technically challenging; some experts question patients' abilities to provide consent, arguing that they cannot weigh the benefits and risks of data sharing and should not be burdened with ethical assessments and decisions about how and by whom data are used.^{198,199} Some also worry that strengthening consent may reduce the quantity and representativeness of data available to advance public health research.

A middle ground between no consent and consenting to everything may be the use of a Data Governance Board to adjudicate requests for data access. The US Food and Drug Administration, for instance, has called for "patient-mediated data-sharing" whereby patients voluntarily share EHR data directly with a Food and Drug Administration Coordinating Center controlled by a patient-elected board.²⁰⁰ Such boards are not without challenges. Medical data often represent a wide variety of conditions and populations that may not be easily distillable into a few patient representatives. Moreover, patients with similar diseases are heterogeneous in their experiences, backgrounds, and needs. Transparency in board decision making and patient involvement are important to the legitimacy of Data Governance boards. Public health emergencies can necessitate and justify rapid access to EHR data. In addition, a governance board can likely respond quickly to emergency data requests.

5. Hospitals and health systems should generally avoid exclusive licensing of their data sets for research because this can limit their use for advancing public health goals.

Rationale: In some cases, hospitals and health systems and those receiving data (such as pharmaceutical companies) are limiting data access out of financial self-interest, through the use exclusive corporate licensing agreements, despite researchers in academia, government, and industry needing adequate access to data to fully achieve the benefits of health data sharing. Registries and health systems have, in some cases, engaged in exclusive data-sharing agreements.^{201,202} Avoidance of sharing data with only the highest financial bidder not only is generally fair but also can help maximize the advancement of public good from medical information.

2.4.6. Recommendations: Social Justice and Racism

1.	The Liaison Committee on Medical Education and the ACGME should require a course on social justice, race, and racism as part of the first-year curriculum of every medical school that they accredit.
2.	Medical schools, graduate medical education (GME) programs, and medical professional organizations should support their students, trainees, and members to engage in allyship and antiracism action.
3.	Medical schools and GME programs should expand the experience of their medical students and trainees by facilitating longitudinal immersion in and partnership with surrounding communities.
4.	An aspect of institutional, local, regional, or national history should be incorporated into every medical school curriculum, every GME program, and every annual meeting of a medical association that offers continuing medical education.
5.	The core set of data collected from each patient encounter should include social determinants of health, including patient race and ethnicity, zip code of residence, and primary language.
6.	Clinicians should review their own practices at least once per year for possible differential treatment of patients by race and ethnicity, zip code, and primary language.
7.	Each healthcare setting should conduct an annual review to answer the question "How is racism operating here?" by examining its structures, policies, practices, norms, and values to identify levers for intervention.

1. The Liaison Committee on Medical Education and the ACGME should require a course on social justice, race, and racism as part of the first-year curriculum of every medical school that they accredit.

Rationale: There is a distinction between the social determinants of health (including poverty and adverse neighborhood conditions) and the social determinants of equity (including racism, sexism, and other systems of structured inequity). The social determinants of health are those determinants of health and illness that

are outside of the individual, beyond our genes and beyond our individual behaviors. They are the contexts of our lives. It is important to address the social determinants of health and illness if we want to have large and sustained improvements in health outcomes. The social determinants of equity and inequity are systems of power that can determine the range of contexts and differentially distribute different populations into different contexts. All Americans are entitled access to quality health care. It is important to address the social determinants of equity and inequity if we are to eliminate health disparities and achieve social justice.

Racism and social injustice are public health problems. Race is the social interpretation of how one looks in a race-conscious society.⁵⁷ It is not written in our genes. The core curriculum should include a review of the history of ideas of biological determinism. Race is not biology. It is the socially assigned substrate on which racism operates. Race-associated differences in the distribution of wealth, income, education, housing, and other measures of social class do not just happen but are the result of historical injustices that are perpetuated by present-day contemporary structural factors.

In contrast, racism is the system of structuring opportunity and assigning value on the basis of the social interpretation of how one looks (which is what we call race). It unfairly disadvantages some individuals and communities, unfairly advantages other individuals and communities, and saps the strength of the whole society through the waste of human resources.⁵⁷ Racism is the root cause of race-associated differences in health outcomes.²⁰³ Racism is a system of power, not an individual character flaw, personal moral failing, or psychiatric illness. Racism operates in 2 ways: to structure opportunity and to assign value. Racism structures opportunity and assigns value according to how a person looks and results in conditions that unfairly advantage some and unfairly disadvantage others. Racism hurts the health of our nation by denying some people the opportunity to attain their highest level of health.

2. Medical schools, GME programs, and medical professional organizations should support their students, trainees, and members to engage in allyship and antiracism action.

Rationale: Racism affects health on 3 levels: institutionalized (structural), personally mediated (interpersonal), and internalized.²⁰⁴ Of these 3 levels, we must intervene at least on institutionalized (structural) racism to set things right. Antiracism action is a legitimate role of the physician and indeed of all medical professionals. Allyship is the practice whereby a person or group in a privileged position or position of power seeks to operate in solidarity with a marginalized person or group. Antiracism action has 3 tasks: name racism; ask "How is racism operating here?"; and organize and strategize to act to end racism.⁵⁷

3. Medical schools and GME programs should expand the experience of their medical students and trainees by facilitating longitudinal immersion in and partnership with surrounding communities.

Rationale: One possible practice model that can be introduced is community-oriented primary care. Aspects of this model include 1) taking responsibility for the health and well-being of a geographically defined community; 2) efforts to go beyond simply providing excellent clinical care to the patients who enter their doors to also identify and address unmet and even unrecognized health needs; 3) strong, respectful partnership between the health institution and its geographically defined community of service; and 4) hiring, training, and deployment of community health workers.

The priorities of the community must guide the work of the health institution. It should use its knowledge, standing, and political connections to advance the health-related and broader interests of the community, recognizing that health is not created within the health sector. The hiring, training, and deployment of community health workers should be implemented and taught. The roles of community health workers should extend beyond patient navigation to include regular home visitation (for health checks, health education, environmental scans, connections to resources); identification of community resources and community needs; planning of community interventions (group classes, health courses, community organizing); planning, implementation, and interpretation of community surveys; and other roles.

4. An aspect of institutional, local, regional, or national history should be incorporated into every medical school curriculum, every GME program, and every annual meeting of a medical association that offers continuing medical education.

Rationale: Overcoming health disparities and achieving health equity cannot be achieved without clinicians understanding and acknowledging the history of discrimination and racism in health care in this country. The long legacy of abuse in medical experimentation and the history of the inhumane use of enslaved African descendants in the United States for medical research have been well chronicled.²⁰⁵ Historical events such as the Tuskegee syphilis study are the roots of many current healthcare obstacles such as low participation in medical research trials and low vaccination rates among Black individuals.²⁰⁶ Physicians must understand the impact of the Flexner Report, which led to closure of all but 2 Black medical schools in 1910.²⁰⁷ Indeed, understanding that this history is inextricably tied to understanding American history is foundational to appreciating the findings of the NAM that lower-quality

treatment of racial minorities and healthcare disparities are the result of “bias, prejudice, and stereotyping on the part of medical professionals.”²⁰⁸ It is foundational to the development of allyship.

5. The core set of data collected from each patient encounter should include social determinants of health, including patient race and ethnicity, zip code of residence, and primary language.

Rationale: The core data set collected from each patient encounter should include patient self-identified race and ethnicity using categories defined by the US Census, zip code of current residence, and primary language. With the development of standardized definitions, other social determinants of health (eg, education level, social support, or physical environment) might also be included.

6. Clinicians should review their own practices at least once per year for possible differential treatment of patients by race and ethnicity, zip code, and primary language.

Rationale: Possible markers of quality of patient care include prescription practices, patient wait times, face time with the patient, and number and nature of referrals.

7. Each healthcare setting should conduct an annual review to answer the question “How is racism operating here?” by examining its structures, policies, practices, norms, and values to identify levers for intervention.

Rationale: The mechanisms of racism include structures, policies, practices, norms, and values:

- Structures: the who, what, when, and where of decision making
- Policies: the written how of decision making
- Practices and norms: the unwritten how of decision making
- Values: the why of decision making

The staff, patients, and community members should engage in the annual review, identify levers for intervention, develop action plans, and monitor progress on past and current action plans.

2.4.7. Caveats

In some cases, competing ethical principles such as beneficence, nonmaleficence, and justice supersede the importance of autonomy or privacy. In such cases, the recommendations in the preceding text may require modification.

With respect to patient-centered care and SDM, patient autonomy does not require the provision of any care requested by a patient. For example, if the chosen therapy is known to be more harmful than beneficial or is futile, the principle of nonmaleficence may justify withholding some types of care. In such cases, the clinician must engage patients and their families in discussions that provide the rationale for the decision.

Achieving public health goals, particularly in the context of public health emergencies, may require a shift in focus from traditional principles focusing on the individual to those focused on community or population benefit. For example, limited resources can create an environment where it is difficult or impossible to honor a patient’s wishes. Perhaps the most dramatic illustration of this issue arose during the coronavirus disease 2019 (COVID-19) pandemic, when the need for ventilators and other critical care resources could have outstripped the available supply. This emergency resulted in prospectively developed principles of allocation grounded on the ethical principle of justice that specifically prohibits the involvement of the clinician(s) caring for an individual patient under consideration.²⁰⁹ The principle of justice on a societal level also underlies decisions about transplantation of hearts and other organs, for which structured rules have been developed in the hopes of ensuring just distribution based on clinical need.²¹⁰

The above examples are stark; given the unsustainable trajectory of health spending in the United States, the tension between autonomy and justice will only increase throughout medical practice. Nevertheless, clinicians should not be placed in a position to balance the benefits of a treatment with the societal opportunity costs of providing care. Ultimately, it is a societal responsibility to determine this balance when scarcity may prohibit the delivery of the care determined to be in the best interests of the individual patient.

Countervailing forces of privacy and public health can arise when considering health data. Again, determinations about the public good that might be served with health data cannot be relegated to individuals, clinicians, or single institutions. Principles developed by competent and educated parties, ideally with the contribution of the patient perspective, should govern the balance between the right to privacy and the interests of public health.

2.5. Task Force 5: Modern Healthcare Delivery: Challenges Related to New Care Delivery Systems

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Medicine is experiencing unprecedented change driven by scientific and technological advances combined with

evolving healthcare delivery systems. Systems of care, research, education, and leadership have been disrupted by sociological, technological, and economic factors. Such changes lie in contrast to the enduring obligation of clinicians to exhibit respectful and moral behavior.¹⁵⁶

The highest moral imperative and ethical principles should be evident consistently in all professional engagements, interactions with peers, and especially interactions with patients. Professionalism is “outward-looking not inward-looking, having nothing to do with the self-serving interests of doctors and everything to do with protecting patients and members of the public.”²¹¹

Evolution in medicine presents opportunity and challenge. Remote meetings in lieu of in-person gatherings (accelerated by the COVID crisis), telemedicine instead of clinic visits, and remote monitoring instead of diagnostic testing have dramatically changed the interactions between clinicians and their patients. Abrupt changes in business models have spurred new tensions in the traditional hospital–practicing physician axis and have led to a diverse range of care models. These can include physician employment, healthcare system consolidation, direct care of patients by insurers, alternate venues of care (pharmacies and big-box stores), and care by a variety of nonphysician clinicians: advanced practice providers, pharmacists, and others. These new challenges are amplified by the growth of EHRs and the increasingly complex billing, coding, documentation, and reimbursement burdens on clinicians. The potential impact of all of these changes on the patient-first or patient-centric mission is evident.

In addition to interactions with patients and other clinicians, engagement with outside partners must respect the highest ethical bar. Such partners can include industry; local, regional, and national regulatory authorities; and professional governing bodies. There must be awareness of the need for integrity in interactions that could be influenced by goals that go beyond those that are patient-centered and reflect either business imperatives or regulatory authority expectations. Finally, the interface with information science, data, and documentation must be honest, accurate, and timely.

Reaffirming the standards for both ethics and professionalism is necessary in the execution of mission statements, strategic goals, and tactical aims. An important example is in the context of achieving the Triple Aim and Quadruple Aim. Based on the Triple Aim,²¹² which focuses on responsibilities to patients and society, the Quadruple Aim⁹³ adds in the dimension of clinician wellness. Potential tension between the needs of the patient and the clinician is complicated and must be reconciled. Regardless of such complexities, it is imperative that clinician wellness cannot be at the expense of patient-centric care.

Clinicians must be trustable and trustworthy, especially when engaged with the most vulnerable, most marginalized, and most underrepresented in the population. As

professionals who facilitate health and, when needed, restore health, it is important to respect the trust equation. Unintended attitudes may convey subconscious biases. Clinicians in positions of authority must constantly manage the expression of attitudes and actively surveil behaviors (ie, practice self-awareness) to avoid the creation of scenarios or environments that exclude others or fail to equitably represent all stakeholders.

Servant leadership among healthcare professionals is essential to meld process, science, and patient-centricity and as a positive influence on society.²¹³ In this very important domain, behaviors, conduct, and attitudes are particularly important because decisions made about others or about strategic objectives may have a broad and significant impact. Recognition of the importance of leadership and its impact in the context of professionalism and ethics is crucial both in and outside of the workplace.²¹¹

Increasingly, as health care, especially cardiovascular care, is practiced by coordinated teams of individual clinicians within highly integrated systems of care (independently of employment model), the inevitable question about professionalism and ethics is, “Do the same standards and expectations that apply to individual professionals apply to the collective professional enterprise as a whole?” The answer must be “yes.” Those same characteristics that define ethical care and clinicianism as they apply to the individual apply to systems of care. The altruistic behaviors, the dedication to honesty and transparency, the avoidance of COIs, the focus on patient-centeredness, the commitment to equity and fairness, and the efforts to dismantle healthcare disparities, which define ethical care and clinicianism as they apply to the individual, must be expected of all healthcare systems.

2.5.1. Addressing Potential COIs When Designing and Engaging in New Models and Venues of Cardiovascular Care Delivery

1.	Clinicians must balance the interests of patients and the stewardship of valuable resources through transparency, focus on quality, SDM, and patient-centeredness in the development and implementation of new models of care delivery.
2.	In the transition from a fee-for-service model of care to one focused on value, clinicians must recognize and weigh the conflicting risks of overtreatment versus undertreatment.
3.	Clinicians with financial interests in alternative sites of care (eg, ambulatory surgery centers, office-based laboratories, physician-owned specialty hospitals) must fully disclose such relationships to patients and must demonstrate that these sites deliver an equal or superior level of care compared with other facilities.
4.	Clinicians should objectively apply appropriate use criteria (AUC) and clinical practice guidelines (CPGs) in the evidence-based care of individual patients while avoiding potential COIs in their development and in their application in value-based models of care.

1. Clinicians must balance the interests of patients and the stewardship of valuable resources through transparency, focus on quality, SDM, and patient-centeredness in the development and implementation of new models of care delivery.

Rationale: Three of the most important changes to the delivery of cardiovascular care (and 3 potential challenges to professionalism) in the past decade have been the employment of physicians by healthcare systems, the evolution of team-based care, and the development of alternative payment models. Clinicianism is by definition altruistic but has shied away from addressing the economic realities of care to achieve the Quadruple Aim, viewing such considerations as a threat to ethical practice and personal professionalism. The current environment requires that healthcare professionals recognize the cost to the patient and to society, as well as realistically addressing the economic sustainability of practice and the ability to deliver care. These potential conflicts can be mitigated through transparently acknowledging direct and indirect incentives or disincentives that translate into how a patient or population of patients are treated. This can be facilitated through SDM that identifies what patients value in their care and by using objective (performance and outcome) measures of clinical quality.^{214–216}

2. In the transition from a fee-for-service model of care to one focused on value, clinicians must recognize and weigh the conflicting risks of overtreatment versus undertreatment.

Rationale: Today's healthcare enterprise defines a matrixed financial relationship among patient, payer, health system, and clinician that is fraught with the potential for COIs and ethical challenges at each intersection. Conflicts may arise through implicit and explicit personal gain to a physician, manifest as compensation based on cost savings and reduced use, contingency of employment, and stearage of patient referrals. The prevailing fee-for-service model of care carries the opposite inherent COIs. More testing or procedures benefit the clinician or hospital but may not benefit the patient: the "sin of commission."^{217–219}

Value-based models, including accountable care organizations and bundled payments, that overemphasize cost containment may compromise quality or patient satisfaction while financially benefiting health systems, hospitals, payers, or practitioners: the "sin of omission."

Physicians overseeing formulary or supply-chain issues should disclose any COIs and recuse themselves from such decisions. Physician leadership in health systems should ensure transparency, build consensus among all stakeholders, including patients and the entire care team, and advocate against overreliance on

financial incentives for both the institution and individual physician that may compromise clinician professionalism and ethical care.²²⁰

3. Clinicians with financial interests in alternative sites of care (eg, ambulatory surgery centers, office-based laboratories, physician-owned specialty hospitals) must fully disclose such relationships to patients and must demonstrate that these sites deliver an equal or superior level of care compared with other facilities.

Rationale: Recently, CMS has approved coverage for certain cardiovascular procedures in freestanding ambulatory surgery centers with the stated goals of improved access to care and lower cost.²²¹ Clinicians who practice in these locations may have full or partial ownership, creating the potential conflicts of self-referral and overuse of care for personal gain.²²² Despite the concerns of COIs, physician-owned facilities may deliver value to patients and payers, including CMS, by improving access, incentivizing efficiencies of care, focusing on patient satisfaction, offering lower cost per case, and promoting physician engagement in overall care delivery ("skin in the game").²²³

Delivery of care in physician-owned ambulatory surgery centers, office-based laboratories, or specialty hospitals must be done with full, easy-to-understand disclosure to the patient before treatment and must meet all state and federal regulations governing self-referral, including Stark Law exemptions. Referrals to alternative sites of care with physician ownership should not be influenced by type of healthcare coverage or insurance. To rationalize care in an alternative physician-owned facility, in addition to lower cost of care, patients should expect equal or better objectively measured quality of care, a superior patient experience, reduced barriers to care, and full knowledge of the physician's interests in the physician-owned site of care.

4. Clinicians should objectively apply AUC and CPGs in the evidence-based care of individual patients while avoiding potential COIs in their development and in their application in value-based models of care.

Rationale: Tools founded on clinical research and expert consensus are available that can objectively help direct clinical decision making that is patient-centered and may reduce personal and system COIs. Such tools include AUC to guide testing and procedural care and CPGs to support the evaluation and treatment of patients with select cardiovascular disorders. AUC, CPGs, and clinical decision support mechanisms are derived from the study of populations of patients and must be applied carefully in the care of unique individual patients.^{224–226} Development of these evidence-based tools must be done with full disclosure of any personal

or professional COIs by those contributing to the guidelines.²²⁷ AUC, CPGs, and clinical decision support mechanisms should not be used to withhold testing or treatment solely on the basis of efforts to reduce cost within value-based models of care.

2.5.2. Medical Professionalism for the Employed Clinician

1.	Patient-centered care, including patient goals and preferences, must be prioritized among quality metrics in pay-for-performance programs.
2.	Guideline-recommended, evidence-based treatment should take into consideration patient preferences and goals.
3.	Implementation of health policy intended to improve value should be supported by high-quality evidence that it improves outcomes and avoids unintended consequences.
4.	Quality, outcomes, patient experience, and the reduction of unnecessary tests and procedures are the responsibility of the clinician and must be given high priority.

1. Patient-centered care, including patient goals and preferences, must be prioritized among quality metrics in pay-for-performance programs.

Rationale: Patient-centered care includes the notion that patients desire to be involved in decisions about their health care. Meaningful conversations with patients require clinicians to acquire the knowledge, skills, and competencies to engage patients of diverse cultural backgrounds, socioeconomic status, and education.²²⁸ Health-related decisions made collaboratively between the patient and clinician integrate available evidence of efficacy and safety and the patient's preferences and values. This process includes introducing choice, describing options, and exploring patient preferences in order to make shared decisions.²²⁹

Among the aims of quality proposed by the Committee on the Quality of Health Care in America of the NAM in its treatise *Crossing the Quality Chasm: A New Health System for the 21st Century*¹⁵⁸ is patient-centered care, defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." Pay-for-performance programs, also known as value-based payment programs, include financial incentives for efficient, high-quality care. Pay-for-performance programs that reward select quality measures have the potential to create ethical COIs for clinicians if these interfere with the delivery of comprehensive care and fail to account for patient-specific circumstances and goals of care. However, these concepts are not necessarily in conflict with each other if performance measures, as described by the NAM, include "measures of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity."¹⁵⁸ The AMA's principles and guidelines note

that fair and ethical pay-for-performance programs are patient centered and link evidence-based performance measures to financial incentives.²³⁰

2. Guideline-recommended, evidence-based treatment should take into consideration patient preferences and goals.

Rationale: ACC/AHA CPGs provide a foundation for the delivery of quality cardiovascular care. Guideline recommendations are based on systematic methods to evaluate and classify evidence, with the highest level of evidence resulting from high-quality randomized clinical trials.³⁶ These recommendations typically reflect findings from trials of large populations meeting specific inclusion and exclusion criteria. They do not necessarily account for patient-specific considerations, including goals of care, concerns about side effects, burdens imposed by the intensity of management, and cost.²³¹ Clinicians should discuss recommendations based on the best available evidence, including expected efficacy outcomes, potential adverse effects of treatment, and alternative approaches, and incorporate patient goals and priorities when developing a management plan.

3. Implementation of health policy intended to improve value should be supported by high-quality evidence that it improves outcomes and avoids unintended consequences.

Rationale: CMS has implemented prospective payment systems and policies that tie reimbursement to the value of care.²³² These value-based programs are intended to improve quality and safety while reducing healthcare costs. Affirmation of the efficacy of these programs requires accurate collection of data and systematic evaluation of quality measures to ensure that these programs improve the delivery of care and health outcomes. It is also important to monitor and avoid the occurrence of unintended consequences. These might include penalties for hospitals caring for patients with multiple comorbidities and socioeconomic disadvantages,²³³ as well as unforeseen adverse patient outcomes. An intention of the Hospital Readmission Reduction Program, in which hospitals incur financial penalties for higher-than-expected 30-day readmission rates for patients with several medical conditions, including heart failure, acute myocardial infarction, and pneumonia, is to favorably affect healthcare expenditures.²³⁴ Whether the program improves outcomes is controversial.^{235,236} An observational analysis of hospitalized patients with myocardial infarction from the National Cardiovascular Data Registry Acute Coronary Treatment and Intervention Outcomes Network Registry–Get With the Guidelines Centers reported that 30-day risk-adjusted readmission rates for myocardial infarction were not associated with adherence to performance of measures or clinical outcomes occurring after the first 30 days after discharge,²³⁷ and an analysis found that quality of care and clinical outcomes were comparable among

hospitals with high versus low risk-adjusted 30-day heart failure readmission rates.²³⁸ In addition, some retrospective studies of Medicare fee-for-service beneficiaries have found that the Hospital Readmission Reduction Program was associated with increased mortality within 30 days of discharge among Medicare beneficiaries hospitalized for heart failure, although others have not confirmed this finding.^{239,240}

4. Quality, outcomes, patient experience, and the reduction of unnecessary tests and procedures are the responsibility of the clinician and must be given high priority.

Rationale: Consolidation of health services includes mergers of multiple hospitals or integration of outpatient centers, physician groups, ambulatory clinics, rehabilitation services, nursing homes, and home health agencies into 1 health system.²⁴¹ Potential benefits of consolidation include improvements in quality, efficiency, and outcomes as a result of increased size of clinical services and subspecialty availability; investment in quality programs; and cost savings through coordination of care delivery. Potential harms include higher prices for payers, higher use of costly tests and procedures, and less innovation attributable to reduced competition.^{241,242}

A recent study using Medicare claims and Hospital Compare data found that hospital acquisition by another hospital or hospital system was associated with modestly worse patient experiences and no significant changes in 30-day hospital readmission or mortality rates.²⁴³ Another potential consequence of consolidation is reduced access to care, particularly if competition causes smaller hospitals in rural communities to close.²⁴⁴ This may limit opportunities for preventive and longitudinal care for chronic conditions and affect the timely assessment of and intervention for urgent conditions such as acute myocardial infarction.

Prioritization of quality, outcomes, and patient experience may require modification of payment models. A retrospective cohort study of patients with coronary artery disease in the PINNACLE Registry (Practice Innovation and Clinical Excellence) assessed differences in evidence-based secondary prevention treatments between those enrolled in the Medicare Advantage plan, which incentivizes performance on evidence-based care, and those enrolled in traditional fee-for-service Medicare.²⁴⁵ Those enrolled in Medicare Advantage were more likely to receive secondary prevention treatments. However, in a retrospective cohort of patients hospitalized with heart failure in hospitals participating in the Get With The Guidelines–Heart Failure registry, there was no difference in receipt of evidence-based heart failure medications or in-hospital mortality between patients enrolled in Medicare Advantage and those in traditional fee-for-service Medicare.²⁴⁶

The clinician must take responsibility for reducing the use of unnecessary tests and procedures.²⁴⁷ A *Consumer Reports* readers' survey found that 44% of healthy adults received screening tests for heart disease deemed unlikely to have benefits that outweigh the risks.²⁴⁸ The Choosing Wisely campaign, initiated by the American Board of Internal Medicine Foundation along with 9 professional societies, including the ACC, identified tests and procedures prone to overuse and provides information about when these tests or procedures may be appropriate.²⁴⁹ Tests and procedures that are not clearly indicated have the potential for harm to patients and drive up the cost of health care. Clinicians and systems must be aware of the influence (real or perceived) of legal risk mitigation in ordering patterns. Efforts to mitigate such risks through the use of guideline-directed medical care, local algorithms (development of appropriate community standards), and legislative influence are needed. Patient education to offset incomplete and inaccurate messaging (often from the internet) is the ultimate responsibility of the clinician but can be aided by local, state, and national systems and organizations.

2.5.3. Ethical Challenges and Professionalism Related to Billing, Coding, Documentation, and EHRs

1.	Clinical documentation should capture the patient's active problems, history, assessment, and medical decision making in a manner that is accurate, current, respectful, consistent, confidential, secure, and transparent.
2.	Clinical coding and billing practices should be supported by verified and audited clinical documentation readily available in the medical record that adheres to <i>International Classification of Diseases, 10th Revision</i> conventions and <i>Current Procedural Terminology</i> rules.
3.	The primary role of an EHR is to facilitate patient care, and this purpose should not be impeded or usurped by the billing, regulatory, research, documentation, or administrative functions of the EHR.
4.	Routine audits of EHRs and clinical documentation should be performed to promote professionalism, ethical practice, and optimal patient care.

1. Clinical documentation should capture the patient's active problems, history, assessment, and medical decision making in a manner that is accurate, current, respectful, consistent, confidential, secure, and transparent.

Rationale: Information housed within an EHR belongs to and should be accessible to the patient. In addition to the patient, access to protected health information should be restricted to only physicians, clinicians, and staff directly responsible for the care of the patient, unless otherwise authorized by the patient's release of information.²⁵⁰

Ethical and professional concerns surrounding the use or misuse of EHRs relate to vulnerability of protected

health information, security breaches, unintended perpetuation of inaccurate information, enabling upcoding and cloning, distraction from direct patient interaction, and loss of clinical context by translating an inherently analog process into a digital or binary one.²⁵¹ Use of the EHR is consistently cited as a leading cause of burnout and an impediment to clinician well-being.²⁵² Clinicians report that the use of EHRs limits time for direct patient interaction and interferes with a key component of medical professionalism. Efforts to reduce these burdens of care created by EHRs should be addressed through advocacy, education, operational optimization, and dialogue with EHR vendors.

Documentation should adhere to principles of patient-centeredness and patient welfare, respect and awareness, truthfulness and accuracy, privacy and security, and transparency and disclosure.²⁵³ Documentation should be clear, concise, thorough, legible, organized, verifiable, and completed in a timely manner. Data should be consistent across all components of the medical record, and when this goal is not achieved, inconsistencies and their origin should be identified and reconciled. Patient safety should be a primary goal of documentation. The use of medical scribes may facilitate entry of clinical information into the EHR, allowing more personal interaction between the patient and the clinician. All information collected and recorded by the scribe must be reviewed and accuracy must be attested to by the responsible clinician. "Copying and pasting" (cloning) should be used judiciously. All information copied and entered into the medical record should be reviewed and edited with each encounter to ensure that it is accurate, relevant, and current.

2. Clinical coding and billing practices should be supported by verified and audited clinical documentation readily available in the medical record that adheres to *International Classification of Diseases, 10th Revision* conventions and Current Procedural Terminology rules.

Rationale: Appropriate clinical coding and associated clinician billing must be supported by accurate and verifiable clinical documentation. The level of billing should be commensurate with the breadth of historical elements, the extent of physical examination, a review of relevant clinical data, and the complexity of clinical decision making and should be consistent with clinician time.²⁵⁴ The volume of documentation should not be a determinant of the level of billing. Extraneous and unnecessary information should not be included in the medical record solely for the purpose of enhancing the level of billing (upcoding). Diagnoses for all reported coding and billing functions

should adhere to the *International Classification of Diseases, 10th Revision* Clinical Modification Procedural Coding System. Billing the correct level of evaluation and management requires the selection of the Current Procedural Terminology code that best represents the patient type, site of service, and level of service rendered.^{255,256} Clinicians and staff should complete necessary initial and continuing education on current billing and coding practices, receive legal and compliance updates, and have constructive feedback through regular audits and reviews. Practices, hospitals, and health systems should have well-defined policies and procedures to guide ethical coding and billing practices.

3. The primary role of an EHR is to facilitate patient care, and this purpose should not be impeded or usurped by the billing, regulatory, research, documentation, or administrative functions of the EHR.

Rationale: One of the most important things clinicians can offer patients is undivided attention. The use of templates and clicks cannot replace the duty to obtain the patient's story through undistracted listening. EHRs need to support the role of shared clinical decision making via easy-to-navigate educational materials and the ability to document the process.⁸ Patients must have easy access to their own health information housed within the EHR to enhance and elevate their role in their care. Structured data should be used when appropriate to measure and collect data elements.

4. Routine audits of EHRs and clinical documentation should be performed to promote professionalism, ethical practice, and optimal patient care.

Rationale: Accuracy of clinical documentation, appropriateness of coding, commensurate level of billing for services rendered, and timely completion of supporting medical records should be audited on a regular basis to provide constructive feedback and education to physicians and care team members and to ensure compliance with all internal policies and external regulations.²⁵⁷

Effective audits can identify the need to refund adjusted claims when necessary, to provide discrete clinical data for patient population health management, and to support process improvement. EHRs must support team-based care via design and outcome. SDM and documentation of all members of the team must be recorded in such a way as to promote the team approach while making the documentation easy to find and use in decision making. This must be done to enable patient teams to contribute to the goal of enhanced patient care. Patient portals must be bidirectional between the patient and the clinician.

2.5.4. Quadruple Aim: Does an Ethical and Professional Perspective Enhance or Obstruct Patient Satisfaction, Outcomes and Quality, Cost, and Clinician Satisfaction?

1.	Continuous assessment of clinician satisfaction and well-being is essential for achieving the Quadruple Aim. Healthcare organizations should implement programs to address and avoid clinician burnout so that the Triple Aim can be optimally achieved.
2.	Although clinician well-being is acknowledged as an essential condition for achieving the Quadruple Aim, the focus on clinician satisfaction must not detract from achieving the Triple Aim for patients.

1. Continuous assessment of clinician satisfaction and well-being is essential for achieving the Quadruple Aim. Healthcare organizations should implement programs to address and avoid clinician burnout so that the Triple Aim can be optimally achieved.

Rationale: The primary goal of the Triple Aim is to improve the health of the population while enhancing patient satisfaction and reducing the cost of care.^{92,258} Although this has been widely accepted in medicine, it has also been noted that achieving these 3 aims can be adversely affected by the stressful work life of healthcare clinicians and staff. This recognition that burnout of clinicians impedes achievement of the Triple Aim has led to adoption of a fourth aim, clinician satisfaction, hence the Quadruple Aim.^{93,259} The addition of clinician satisfaction is recognition that this is an essential condition for achieving the Triple Aim. Whereas 3 objectives of the Quadruple Aim are the *raison d'être* of health organizations and systems, the fourth is an essential condition for achieving them.

Achievement of the fourth aim has been made particularly challenging by the tedious and time-consuming nature of EHRs.²⁶⁰ The transition to EHRs has been a particularly strong contributor to the frustration, dissatisfaction, stress, and exhaustion of clinicians.^{95,261} Healthcare organizations can work toward achieving the fourth aim by improving the work life of clinicians and staff.²⁶² Some of the measures that can be implemented include team documentation in the EHR, pre-visit planning, and testing, allowing each team member to practice at the top of their licenses, and standardization of workflows.

2. Although clinician well-being is acknowledged as an essential condition for achieving the Quadruple Aim, the focus on clinician satisfaction must not detract from achieving the Triple Aim for patients.

Rationale: Health care may include inherent conflict between the parts of the Quadruple Aim: how to improve clinician well-being and productivity while still reducing costs and improving population health and the patient experience.⁹³ If the emphasis on the well-being

of the workforce comes at the expense of patients' needs, there will be negative consequences for patient-centered care. However, working toward achieving the Triple Aim may actually increase physician burnout and thereby reduce the chances of success. Clinician burnout potentially imperils the Triple Aim by leading to lower patient satisfaction, a reduction in healthcare outcomes, and increased cost. Health care is a relationship between those who provide care and those who seek care, and the proper balance can be struck only if it is a symbiotic one benefitting both parties.

2.5.5. Conclusions

Delivery of cardiovascular care to people and communities continues to evolve rapidly, whereas professional obligations to patient-centricity must remain consistent. The transformation of care delivery models and the complexities of new technologies mandate increased attention and careful introspection in relationship to professionalism and ethics. Evolving employment and payment models, rapidly changing delivery sites of care, and the documentation of care require maintenance of standards that are beyond reproach and representative of the trust placed in all physicians and clinicians. It is the responsibility of each individual, as well as our professional communities, to continually evaluate the degree to which such standards are maintained and met.

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Appendix 1. Author Relationships With Industry and Other Entities (Comprehensive)—2020 American Heart Association and American College of Cardiology Consensus Conference on Professionalism and Ethics: A Consensus Conference Report



Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Ivor J. Benjamin	Medical College of Wisconsin—Director for the Cardiovascular Research Center, Vice Chair for Translational Research Medicine, Professor of Medicine, Physiology, Pharmacology & Toxicology, Cell Biology & Surgery	None	None	None	None	None	None
C. Michael Valentine	University of Virginia—Professor of Medicine, Cardiovascular Division	None	None	None	None	None	None
Richard E. Anderson	The Doctors Company chairman and CEO	None	None	None	None	None	None
Emelia J. Benjamin	Assistant Provost for Faculty Development, Vice-Chair, Faculty Development and Diversity Professor of Medicine and Epidemiology, Boston University Schools of Medicine and Public Health	<ul style="list-style-type: none"> OSMB for the NIH CARDIA STUDY (modest) Starting 2020, uncompensated member for MyHeartLab Steering Committee, a PI-initiated study from Samsung to UCSF. PI, Jeffrey Olgin, MD (modest) 	None	None	<ul style="list-style-type: none"> NIH: R01HL128914; 2R01 HL092577; 1R01 HL141434 01A1; 2U54HL120163; 1R01AG066010; (significant) American Heart Association, 18SFRN34110082. (significant) Robert Wood Johnson Grant 74624 (significant) 	<ul style="list-style-type: none"> <i>Circulation</i> Editorial Board (modest) <i>European Heart Journal—International</i> Editorial Board (modest) <i>Nature Reviews Cardiology—Advisory Board</i> (modest) 	None
Cathleen Biga	Cardiovascular Management of Illinois—President & CEO, MedAxiom—Chairman Board of Managers	<ul style="list-style-type: none"> Wiggins Sewell & Ogle-tree (significant) MedAxiom Advisory Board (significant) 	None	<ul style="list-style-type: none"> Aftershock (significant) Cardiovascular Management of Illinois (significant) 	None	None	None

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Ralph G. Brindis	University of California San Francisco—Regional Senior Advisor for Cardiovascular Diseases, Clinical Professor of Medicine, Institute of Health Policy Studies	• Apple (modest)	None	None	• AC Wellness Network (Officer, Director, Trustee, or other fiduciary role) (significant)	• ACCF (salary/ significant) • FDA CV Device Panel (salary/ modest) • State of California DSMB (modest)	None
Bernadette M. Broccoli	McDermott Will & Emery—Partner	None	None	None	None	None	None
Richard A. Chazal	Heart and Vascular Institute Lee Health—Medical Director	None	None	None	None	None	None
Megan J. Coylewright	Dartmouth-Hitchcock Medical Center—Associate Director, Structural Heart Disease Program, Assistant Professor of Medicine, Geisel School of Medicine at Dartmouth, Assistant Professor of Health Policy and Clinical Practice, The Dartmouth Institute	• W.L. Gore (modest)	None	None	• Boston Scientific (significant) • Edwards Lifesciences (significant)	• Trial sponsors: Edwards Lifesciences x2, Boston Scientific (modest)	None
Mark A. Creager	Dartmouth-Hitchcock Medical Center—Director, Heart and Vascular Center, Professor of Medicine, Giesel School of Medicine at Dartmouth	None	None	None	• World Heart Federation (significant)	• Dartmouth-Hitchcock Medical Center (significant)	None
Pamela S. Douglas	Duke University Medical Center—Ursula Geller Professor of Research in Cardiovascular Diseases	• UpToDate (significant) • Elsevier (spouse) (modest) • Konica Minolta (modest) • Pappas Ventures (spouse) (modest)	None	None	• Heartflow Kowa (modest) • Abbott (spouse) (modest) • NIH (self and spouse) (significant) • Partners Healthcare (significant) • Defense Threat Reduction Agency (modest) • Department of Defense/Defense Advanced Research Agency (spouse) (modest)	• Exploragen (spouse) (modest) • Fabric genomics (spouse) (modest) • MeTree and You (modest) • Origin Commercial Advisors (modest) • Peer Medical (modest) • Predigen (modest)	None
John P. Erwin III	Northshore University HealthSystem—Louise W. Coon Chairman, Department of Medicine, Senior Clinician Educator, Priztler School of Medicine	None	None	None	• North Shore University Health System (significant)	None	None
Keith C. Ferdinand	Tulane University School of Medicine—Gerald S. Berenson Endowed Chair in Preventive Cardiology, Professor of Clinical Medicine	• Amgen, Inc (modest) • Boehringer Ingelheim (modest) • Eli Lilly (modest) • Novartis Corp (modest) • Quantum Genomics (modest) • Sanofi-Aventis (modest)	None	None	None	None	None
Edward T. Fry	Ascension Medical Group—Interventional Cardiologist	None	None	• St. Vincent Heart Center of Indiana (significant)	None	None	None
Karen L. Furie	Brown University—Chair of Neurology, Rhode Island Hospital, The Miram Hospital and Bradley Hospital, Chair, Department of Neurology, The Warren Alpert Medical School	None	None	None	None	None	None

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Robert A. Harrington	Stanford University—Arthur L. Bloomfield Professor of Medicine, Chair, Department of Medicine	<ul style="list-style-type: none"> Adverse Events WebMD (significant) 	None	<ul style="list-style-type: none"> Element Science (none) 	<ul style="list-style-type: none"> Signal Path (Evidint) (significant) AHA (significant) 	<ul style="list-style-type: none"> College of the Holy Cross, Worcester, MA (significant) 	None
Sharonne N. Hayes	Mayo Clinic—Professor of Cardiovascular Medicine, Director of Diversity and Inclusion, Women's Heart Clinic	None	None	None	None	<ul style="list-style-type: none"> Biotronik (salary/significant, spouse) 	None
Adrian F. Hernandez	Duke University—Professor of Medicine, Vice Dean and Executive Director of Duke Clinical Research, Executive Core Faculty Member, Duke Margolis Center for Health Policy	<ul style="list-style-type: none"> Amgen, Inc (modest) AstraZeneca Pharmaceuticals (modest) Bayer Corp US (modest) BioFourmis (modest) Boehringer Ingelheim Pharmaceuticals, Inc (modest) Boston Scientific (significant) Cytokinetics (modest) Merck & Co, Inc (modest) MyoKardia (modest) Novartis (significant) Pfizer (modest) Relypsa (modest) Sanofi-Aventis (significant) Xogenex (modest) 	None	None	<ul style="list-style-type: none"> American Regent (modest) AstraZeneca (significant) Daiichi Sankyo (modest) Genentech, Inc (modest) GlaxoSmithKline (significant) Janssen Pharmaceuticals, Inc (modest) Merck & Co, Inc (modest) Novartis (significant) Verily (significant) National Institutes of Health PCORI (modest) 	<ul style="list-style-type: none"> Eidos DSMB (modest) American Heart Association (significant) 	Defendant, Venable Fitzpatrick, patent dispute, 2019 (modest)
Camara P. Jones	Emory University—Adjunct Professor, Behavioral, Social and Health Education, Epidemiology, Rollins School of Public Health Senior Fellow, Satcher Health Leadership Institute and Cardiovascular Research Institute, Morehouse School of Medicine	None	None	None	None	None	None
Willie E. Lawrence Jr	Midwest Heart & Vascular Specialists—Chief of Cardiology, Research Medical Center, Founder and Director, Congestive Heart Failure Program, Director, Cardiac Rehabilitation	None	None	None	None	None	None
Glenn N. Levine	Baylor College of Medicine—Master Clinician and Professor of Medicine, Chief, Cardiology Section, Michael E. DeBakey VA Medical Center	None	None	None	None	None	None
Michael J. Mack	Baylor, Scott & White Health—Medical Director of Cardiothoracic Surgery, Chairman, BSW The Heart Hospital	<ul style="list-style-type: none"> Gore (none) 	None	None	<ul style="list-style-type: none"> Abbott Vascular (none) Edwards Lifesciences (none) MEDTRONIC (none) 	None	None
Frederick A. Masoudi	University of Colorado—Professor of Medicine, Anschutz, Medical Campus	<ul style="list-style-type: none"> American Board of Internal Medicine (modest) TurningPoint (modest) UpToDate (modest) 	None	None	<ul style="list-style-type: none"> John A. Hartford Foundation (significant) 	<ul style="list-style-type: none"> ACCF-NCDR (salary/significant) Massachusetts Medical Society—Associate Editor, <i>Journal Watch Cardiology</i> (modest) 	None

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Appendix 1. Continued

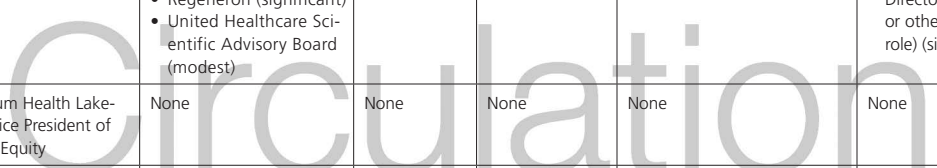
Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Daniel D. Matlock	University of Colorado—Associate Professor of Medicine, Geriatrics, Director of the Colorado Program for Patient Centered Decisions	None	None	None	<ul style="list-style-type: none"> • ACCF Foundation (significant) • Colorado Health Foundation (significant) • NIH (NHLBI, NIA, and NCI) (significant) • The Patient Centered Outcomes Research Institute (PCORI) (significant) 	None	None
Laxmi S. Mehta	The Ohio State University—Professor of Medicine, Section Director of Preventative Cardiology & Women's Cardiovascular Health, Director of Lipid Clinics, Sarah Ross Soter Endowed Chair in Women's Cardiovascular Health	None	None	None	None	<ul style="list-style-type: none"> • AHA National Lipid Association (significant) 	None
Jennifer H. Mieres	Hofstra Northwell School of Medicine—Senior Vice President, Center for Equity of Care, Chief Diversity and Inclusion Officer, Northwell Health, Associate Dean, Faculty Affairs and Professor of Cardiology, Donald and Barbara Zucker School of Medicine	None	None	None	None		None
Jennifer E. Miller	Yale School of Medicine—Professor, Founder, Bioethics International	<ul style="list-style-type: none"> • Ethics Committee, Regeneron Pharmaceuticals. (modest) • Honorarium goes directly to Bioethics International (modest) • Cambria Regency Pharmacy and Therapeutics Committee, ethics advisor (modest) 	None	None	<ul style="list-style-type: none"> • The Laura and John Arnold Foundation (significant) • Milken Institute (significant) 	None	None
Daniel J. Murphy Jr	Stanford University—Professor of Pediatrics (Cardiology) Director, Pediatric Cardiac Clinical Program, Lucille Packard Children's Hospital	None	None	None	None	None	None
William J. Oetgen	Georgetown University—Clinical Professor of Medicine	None	None	None	None	<ul style="list-style-type: none"> • Member and Immediate Past Chairman, Board of Directors, MedStar Health, Inc, Columbia, MD (modest) 	None
Ileana L. Piña	Wayne State University—Professor of Medicine, Central Michigan University—Clinical Professor of Medicine	<ul style="list-style-type: none"> • Novartis Corp (modest) • Relypsa (modest) • Vifor (modest) 	None	None	None	<ul style="list-style-type: none"> • FDA, CDRH (modest) 	None
Athena Poppas	Brown University—Chief, Cardiology Division, Professor of Medicine, Lifespan Cardiovascular Institute—Chief, Cardiology Division, Director, Lifespan Cardiovascular Institute, Director, Echocardiography Rhode Island, the Miriam and Newport Hospitals	None	None	<ul style="list-style-type: none"> • GE Stock (significant) 	None	None	None

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Rita F. Redberg	University of California San Francisco—Professor of Medicine, UCSF School of Medicine, Division of Cardiology	None	None	None	None	• <i>JAMA Internal Medicine</i> (modest)	None
William H. Roach Jr	McDermott Will & Emery, Partner, Retired	None	None	None	• AHA	None	None
Jorge F. Saucedo	Medical College of Wisconsin—Division Chief of Cardiology, Director of Heart and Vascular Services	None	None	None	None	None	None
Katherine A. Sheehan	American Heart Association Science and Medicine Advisor	None	None	None	None	None	None
John A. Spertus	University of Missouri, Kansas City—Daniel Lauer/Missouri Endowed Chair and Professor, Clinical Director of Outcomes Research, Saint Luke's Mid American Heart Institute	<ul style="list-style-type: none"> • Amgen (modest) • AstraZeneca Pharmaceuticals (significant) • Bayer Healthcare Pharmaceuticals (modest) • Copyright for SAQ, KCCQ, and PAQ (significant) • Janssen Pharmaceuticals, Inc (significant) • Merck & Co, Inc (significant) • Novartis (significant) • Regeneron (significant) • United Healthcare Scientific Advisory Board (modest) 	None	<ul style="list-style-type: none"> • Health Outcomes Sciences (significant) 	<ul style="list-style-type: none"> • American College of Cardiology Foundation (significant) 	<ul style="list-style-type: none"> • Abbott Laboratories (modest) • MEDTRONIC (modest) • ACCF (modest) • AHA <i>Circulation: Cardiovascular Quality and Outcomes</i> (significant) • Blue Cross Blue Shield of Kansas City (Officer, Director, Trustee, or other fiduciary role) (significant) 	None
Lynn Todman	Spectrum Health Lakeland—Vice President of Health Equity	None	None	None	None	None	None
Gaby Weissman	Medstar Washington Hospital—Vascular Surgeon	None	None	None	<ul style="list-style-type: none"> • Abbott Laboratories (significant) • Ancora (significant) • Boston Scientific (significant) • LIVANOVA (significant) • MEDTRONIC (modest) 	None	None
Colin P. West	Mayo Clinic—consultant, Department of Internal Medicine	None	None	None	None	None	None
Clyde W. Yancy	Northwestern University—Vice Dean for Diversity and Inclusion, Magerstadt Professor of Medicine; Chief, Division of Cardiology	None	None	None	None	<ul style="list-style-type: none"> • Abbott Laboratories (significant) • <i>JAMA Cardiology</i> (significant) • US federal government, Department of HHS, Advisory Committee on Minority Health (modest) 	None

This table represents the relationships of committee members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the committee are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$5000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$5000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.



Appendix 2. Reviewer Relationships With Industry and Other Entities (Comprehensive)—2020 American Heart Association and American College of Cardiology Consensus Conference on Professionalism and Ethics: A Consensus Conference Report

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Joseph P. Iser	American College of Preventive Medicine—Chair, Ethics Committee	Chief Health Officer, ex officio	None	None	None	None	None	None
Dipti Itchhaporia	American College of Cardiology Foundation	Jeffrey M. Carlton Heart & Vascular Institute—Program Director, Congestive Heart Failure Eric & Sheila Samson Endowed Chair in Cardiovascular Health	None	None	None	None	None	None
Peter Paganos	American Heart Association	Washington University—Professor, Emergency Medicine, School of Medicine	None	None	None	None	None	None
Athena Poppas	American College of Cardiology Foundation	Brown University—Chief, Cardiology Division, Professor of Medicine, Lifespan Cardiovascular Institute—Chief, Cardiology Division, Director, Lifespan Cardiovascular Institute, Director, Echocardiography Rhode Island, The Miriam and Newport Hospitals	None	None	• GE Stock (significant)	None	None	None
Svati Shah	American Heart Association	Duke University—Associate Dean of Genomics Director of the Duke Precision Genomics Collaboratory	None	None	None	None	None	None
Lois Snyder Sulmasy	American College of Physicians	American College of Physicians	None	None	None	None	None	None
Lina Ya'quob	American Heart Association, Early Career	Ochsner-Louisiana State University—Cardiovascular Disease Fellow	None	None	None	None	None	None
Poonam Velagapudi	American College of Cardiology Foundation, Early Career	University of Nebraska Medical Center—Assistant Professor, Internal Medicine Associate Program Director, Cardiovascular Medicine Fellowship, Director, Digital Innovation and Social Media Strategy	None	None	None	None	None	None



This table represents all relationships of reviewers with industry and other entities that were reported at the time of peer review, including those not deemed to be relevant to this document, at the time this document was under review. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥\$5000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetic order within each category of review. Please refer to <https://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy> for definitions of disclosure categories or additional information about the American College of Cardiology/American Heart Association Disclosure Policy for Writing Committees.