OPINIONS OF THE COUNCIL ON COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions were presented by Alexander M. Rosenau, DO, Chair.

1. AMENDMENT TO OPINION 9.3.2, "PHYSICIAN RESPONSIBILITIES TO IMPAIRED COLLEAGUES"

CEJA Opinion. No reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the June 2021 Special Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 3, "Amendment to Opinion 9.3.2, 'Physician Responsibilities to Impaired Colleagues." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the Code of Medical Ethics.

E-9.3.2 – Physician Responsibilities to Colleagues with Illness, Disability or Impairment

Providing safe, high-quality care is fundamental to physicians' fiduciary obligation to promote patient welfare. Yet a variety of physical and mental health conditions—including physical disability, medical illness, and substance use—can undermine physicians' ability to fulfill that obligation. These conditions in turn can put patients at risk, compromise physicians' relationships with patients, as well as colleagues, and undermine public trust in the profession.

While some conditions may render it impossible for a physician to provide care safely, with appropriate accommodations or treatment many can responsibly continue to practice, or resume practice once those needs have been met. In carrying out their responsibilities to colleagues, patients, and the public, physicians should strive to employ a process that distinguishes conditions that are permanently incompatible with the safe practice of medicine from those that are not and respond accordingly.

As individuals, physicians should:

- (a) Maintain their own physical and mental health, strive for self-awareness, and promote recognition of and resources to address conditions that may cause impairment.
- (b) Seek assistance as needed when continuing to practice is unsafe for patients, in keeping with ethics guidance on physician health and competence.
- (c) Intervene with respect and compassion when a colleague is not able to practice safely. Such intervention should strive to ensure that the colleague is no longer endangering patients and that the individual receive appropriate evaluation and care to treat any impairing conditions.
- (d) Protect the interests of patients by promoting appropriate interventions when a colleague continues to provide unsafe care despite efforts to dissuade them from practice.
- (e) Seek assistance when intervening, in keeping with institutional policies, regulatory requirements, or applicable law.

Collectively, physicians should nurture a respectful, supportive professional culture by:

(f) Encouraging the development of practice environments that promote collegial mutual support in the interest of patient safety.

- (g) Encouraging development of inclusive training standards that enable individuals with disabilities to enter the profession and have safe, successful careers.
- (h) Eliminating stigma within the profession regarding illness and disability.
- (i) Advocating for supportive services and accommodations to enable physicians who require assistance to provide safe, effective care.
- (j) Advocating for respectful and supportive, evidence-based peer review policies and practices that will ensure patient safety and practice competency. (II)

REPORTS OF THE COUNCIL ON COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports were presented by Alexander M. Rosenau, DO, Chair:

1. SHORT-TERM MEDICAL SERVICE TRIPS

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: REFERRED

Short-term medical service trips, which send physicians and physicians in training from wealthier countries to provide care in resource-limited settings abroad for a period of days or weeks, have emerged as a prominent strategy for addressing global health inequities. They also provide training and educational opportunities, thus offering benefit both to the communities that host them and the medical professionals and trainees who volunteer their time and clinical skills. At the same time, short-term medical service trips pose challenges for everyone involved. Volunteers, sponsors, and hosts must jointly prioritize activities to meet agreed-on goals; navigate day-to-day collaboration across differences of culture, language, and history; and fairly allocate host and team resources in the local setting.

This report by the Council on Ethical and Judicial Affairs (CEJA) explores the phenomenon of short-term medical service trips and offers guidance for physicians and physicians in training to help them address the ethical challenges they face in providing clinical care in resource-limited settings abroad.

THE APPEAL OF SERVING ABROAD

Just how many clinicians volunteer to provide medical care in resource-limited settings abroad is difficult to estimate, but the number is large. By one estimate, in the U.S. some 21% of the nearly 3 billion dollars' worth of volunteer hours spent in international efforts in 2007 were medically related [1]. For trainees, in January 2015 the Consortium of Universities for Global Health identified more than 180 websites relating to global health opportunities [2]. The Association of American Medical Colleges found that among students who graduated in 2017–2018 between 25% and 31% reported having had some "global health experience" during medical school [3].

A variety of reasons motivate physicians and trainees to volunteer for service trips. For many, compelling motivations include the opportunities such trips offer to help address health inequities, to improve their diagnostic and technical skills as clinicians, or to explore global health as a topic of study [1]. Service trips can also serve less lofty goals of building one's resume and improving one's professional prospects, gaining the esteem of peers and family, or simply enjoying international travel [1].

A NOTE ON TERMINOLOGY

The literature is replete with different terms for the activity of traveling abroad to provide medical care on a volunteer basis, including "short-term medical volunteerism" [4], "short-term medical missions" [5], "short-term medical service trips" [6,7], "short-term experience in global health" [8,9], "global health field experience" [10], "global health experience," and "international health experience" [1]. Each has merit as a term of art.

The Council on Ethical and Judicial Affairs prefers "short-term medical service trips." In the council's view, this term is clear, concrete, concise, and does not lend itself to multiple interpretations and possible misunderstanding. Importantly, it succinctly captures the features of these activities that are most salient from the perspective of professional ethics in medicine: their limited duration and their orientation toward service.

MEDICAL SERVICE IN RESOURCE-LIMITED SETTINGS

Traditionally, short-term medical service trips focused on providing clinical care as a charitable activity, not infrequently under the auspices of faith-based institutions, whose primary goal was to address unmet medical needs [9]. Increasingly, such trips focus on the broader goal of improving the health and well-being of host communities [8]. Many now also offer training opportunities for medical students and residents [8,9,10]. Ideally, short-term medical

service trips are part of larger, long-term efforts to build capacity in health care systems being visited, and ultimately to reduce global health disparities [8,9].

The medical needs of host communities differ from those of volunteers' home countries—volunteers may encounter patients with medical conditions volunteers have not seen before, or who present at more advanced stages of disease, or are complicated by "conditions, such as severe malnutrition, for which medical volunteers may have limited experience" [6]. At the same time, available treatment options may include medications or tools with which volunteers are not familiar.

By definition, short-term medical service trips take place in contexts of scarce resources. The communities they serve are "victims of social, economic, or environmental factors" who have limited access to health care [6], and often lack access to food, and economic and political power as well and "may feel unable to say no to charity in any form offered" [9]. Moreover, short-term medical service trips take place under the long shadow of colonialism, including medicine's role [11], and have been critiqued as perpetuating the colonial legacy of racism, exploitation, and dependency [9,12,13].

ETHICAL RESPONSIBILITIES IN SHORT-TERM MEDICAL SERVICE TRIPS

These realities define fundamental ethical responsibilities not only for those who volunteer, but equally for the individuals and organizations that sponsor short-term medical service trips. Emerging guidelines identify duties to maximize and enhance good clinical outcomes, to promote justice and sustainability, to minimize burdens on host communities, and to respect persons and local cultures [1,8, 9,10].

Promoting Justice & Sustainability

If short-term medical service trips are to achieve their primary goal of improving the health of local host communities, they must commit not simply to addressing immediate, concrete needs, but to helping the community build its own capacity to provide health care. To that end, the near and longer-term goals of trips should be set in collaboration with the host community, not determined in advance solely by the interests or intent of trip sponsors and participants [8,6]. Trips should seek to balance community priorities with the training interests and abilities of participants [9], but in the first instance benefits should be those desired by the host community [8]. Likewise, interventions must be acceptable to the community [8].

Volunteers and sponsors involved with short-term medical service trips have a responsibility to ask how they can best use a trip's limited time and material resources to promote the long-term goal of developing local capacity. Will the trip train local health care providers? Build local infrastructure? Empower the community [6]? Ideally, a short-term medical service trip will be part of a collaboratively planned longer-term and evolving engagement with the host community [6,9].

Minimizing Potential for Harms & Burdens in Host Communities

Just as focusing on the overarching goal of promoting justice and sustainability is foundational to ethically sound short-term medical service trips, so too is identifying and minimizing the burdens such trips could place on the intended beneficiaries.

Beyond lodging, food, and other direct costs of short-term medical service trips, which are usually reimbursed to host communities [8], such trips can place indirect, less material burdens on local communities. Physicians, trainees, and others who organize or participate in short-term medical service trips should be alert to possible unintended consequences that can undermine the value of a trip to both hosts and participants. Trips should not detract from or place significant burdens on local clinicians and resources, particularly in ways that negatively affect patients, jeopardize sustainability, or disrupt relationships between trainees and their home institutions [8,10]. For example, donations of medical supplies can address immediate need, but at the same time create burdens for the local health care system and jeopardize development by the local community of effective solutions to long-term supply problems [6].

Negotiating beforehand how visiting health care professionals will be expected to interact with the host community and the boundaries of the team's mission, skill, and training can surface possible impacts and allow them to be addressed before the team is in the field. Likewise, selecting team members whose skills and experience map to the needs and expectations of the host community can help minimize disruptive effects on local practice [10]. Advance preparation should include developing a plan to monitor and address ongoing costs and benefits to patients and host communities and institutions, including local trainees (when the trip includes providing training for the host community), once the team is in the field [10].

Respecting Persons & Cultures

Physicians and trainees who participate in short-term medical service trips face a host of challenges. Some of them are practical—resource limitations, unfamiliar medical needs, living conditions outside their experience, among many others. Some challenges are more philosophical, especially the challenge of navigating language(s) and norms they may never have encountered before, or not encountered with the same immediacy [1,8]. Striking a balance between Western medicine's understanding of the professional commitment to respect for persons and the expectations of host communities rooted in other histories, traditions, and social structures calls for a level of discernment, sensitivity, and humility that may more often be seen as the skill set of an ethnographer than a clinician.

Individuals who travel abroad to provide medical care in resource-limited settings should be aware that the interactions they will have in the field will inevitably be cross-cultural. They should seek to become broadly knowledgeable about the communities in which they will work, such as the primary language(s) in which encounters will occur; predominant local "explanatory models" of health and illness; local expectations for how health care professionals behave toward patients and toward one another; and salient economic, political, and social dynamics. Volunteers should take advantage of resources that can help them begin to cultivate the "cultural sensitivity" they will need to provide safe, respectful, patient-centered care in the context of the specific host community [6,9,10].

Individuals do not bear this responsibility alone, of course. Organizations and institutions that sponsor short-term medical service trips have a responsibility to make appropriate orientation and training available to volunteers before they depart [10], in addition to working with host communities to put in place appropriate services, such as interpreters or local mentors, to support volunteers in the field.

The ethical obligation to respect the individual patients they serve and their host communities' cultural and social traditions does *not* obligate physicians and trainees "to violate fundamental personal values, standards of medical care or ethical practice, or the law" [8]. Volunteers will be challenged, rather, to negotiate compromises that preserve in some reasonable measure the values of both parties whenever possible [14]. Volunteers should be allowed to decline to participate in activities that violate deeply held personal beliefs, but they should reflect long and carefully before reaching such a decision [15].

GETTING INTO THE FIELD

To fulfill these fundamental ethical responsibilities, moreover, requires meeting other obligations with respect to organizing and carrying out short-term medical service trips. Specifically, sponsoring organizations and institutions have an obligation to ensure thoughtful, diligent preparation to promote a trip's overall goals, including appropriately preparing volunteers for the field experience. Physicians and trainees, for their part, have an obligation to choose thoughtfully those programs with which they affiliate themselves [1,8,9,10].

Prepare Diligently

Guidelines from the American College of Physicians recognize that "predeparture preparation is itself an ethical obligation" [8,cf. 1]. Defining the goal(s) of a short-term medical service trip in collaboration with the host community helps to clarify what material resources will be needed in the field, and thus anticipate and minimize logistic burdens the trip may pose. Collaborative planning can similarly identify what clinical skills volunteers should be expected to bring to the effort, for example, and what activities they should be assigned, or whether local mentors are needed or desirable and how such relationships will be coordinated [10].

Importantly, thoughtful preparation includes determining what nonclinical skills and experience volunteers should have to contribute to the overall success of the service opportunity. For example, a primary goal of supporting capacity building in the local community calls for participants who have "training and/or familiarity with principles of international development, social determinants of health, and public health systems" [9].

Adequately preparing physicians and trainees for short-term medical service trips encompasses planning with respect to issues of personal safety, vaccinations, unique personal health needs, travel, malpractice insurance, and local credentialing requirements [6]. Equally important, to contribute effectively and minimize "culture shock" and distress, volunteers need a basic understanding of the context in which they will be working [1,6]. Without expecting them to become experts in local culture, volunteers should have access to resources that will orient them to the language(s), traditions, norms, and expectations of the host community, not simply to the resource and clinical challenges they are likely to face. Volunteers should have sufficient knowledge to conduct themselves appropriately in the field setting, whether that is in how they dress, how they address or interact with different members of the community, or how they carry out their clinical responsibilities [6]. And they need to know whom they can turn to for guidance in the moment.

Preparation should also include explicit attention to the possibility that volunteers will encounter ethical dilemmas. Working in unfamiliar cultural settings and health care systems poses the real possibility for physicians and trainees that they will encounter situations in which they "are unable to act in ways that are consistent with ethics and their professional values" or "feel complicit in a moral wrong" [8]. Having strategies in place to address dilemmas when they arise and to debrief after the fact can help mitigate the impact of such experiences. In cases of irreducible conflict with local norms, volunteers may withdraw from care of an individual patient or from the mission after careful consideration of the effect withdrawing will have on the patient, the medical team, and the mission overall, in keeping with ethics guidance on the exercise of conscience.

Choose Thoughtfully

Individual physicians and trainees who volunteer for short-term medical service trips are not in a position to directly influence how such programs are organized or carried out. They can, however, by preference choose to participate in activities carried out by organizations that fulfill the ethical responsibilities discussed above [8,9,10]. Volunteers can select organizations and programs that demonstrate commitment to long-term, community-led efforts to build and sustain local health care resources over programs that provide episodic, stop-gap medical interventions, which can promote dependence on the cycle of foreign charitable assistance rather than development of local infrastructure [9].

Measure & Share Meaningful Outcomes

Organizations that sponsor short-term medical service trips have a responsibility to monitor and evaluate the effectiveness of their programs, [8,6,9]. The measures used to evaluate program outcomes should be appropriate to the program's goals as defined proactively in collaboration with the host community [8]; for example, some have suggested quality-adjusted life years (QALYs) [16]. Prospective participants should affiliate themselves with programs that demonstrate effectiveness in providing outcomes meaningful to the population they serve, rather than simple measures of process such as number of procedures performed [6]. Developing meaningful outcome measures will require thoughtful reflection on the knowledge and skills needed to address the specific situation of the community or communities being served and on what preparations are essential to maximize health benefits and avoid undue harm.

RECOMMENDATION

In light of these deliberations, the Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Short-term medical service trips, which send physicians and physicians in training from wealthier countries to provide care in resource-limited settings for a period of days or weeks, have emerged as a prominent response for addressing global health inequities. They also provide training and educational opportunities, thus offering benefit both to the communities that host them and the medical professionals and trainees who volunteer their time and clinical skills.

By definition, short-term medical service trips take place in contexts of scarce resources and in the shadow of colonial histories. These realities define fundamental ethical responsibilities to enable good health outcomes, promote justice and sustainability, minimize burdens on host communities, and respect persons and local cultures. Responsibly carrying out short-term medical service trips requires diligent preparation on the part of sponsors and participants in collaboration with host communities.

Physicians and trainees who are involved with short-term medical service trips should ensure that the trips with which they are associated:

- (a) Focus prominently on promoting justice and sustainability by collaborating with the host community to define mission parameters, including identifying community needs, mission goals, and how the volunteer medical team will integrate with local health care professionals and the local health care system. In collaboration with the host community, short-term medical service trips should identify opportunities for and priority of efforts to support the community in building health care capacity. Trips that also serve secondary goals, such as providing educational opportunities for trainees, should prioritize benefits as defined by the host community over benefits to members of the volunteer medical team.
- (b) Seek to proactively identify and minimize burdens the trip may place on the host community, including not only direct, material costs of hosting volunteers, but on possible disruptive effects the presence of volunteers could have for local practice and practitioners as well. Sponsors and participants should ensure that team members practice only within their skill sets and experience, and that resources are available to support the success of the trip, including arranging for local mentors, translation services, and volunteers' personal health needs as appropriate.
- (c) Seek to become broadly knowledgeable about the communities in which they will work and take advantage of resources to begin to cultivate the "cultural sensitivity" they will need to provide safe, respectful, patient-centered care in the context of the specific host community. Members of the volunteer medical team are expected to uphold the ethics standards of their profession and volunteers should insist that strategies are in place to address ethical dilemmas as they arise. In cases of irreducible conflict with local norms, volunteers may withdraw from care of an individual patient or from the mission after careful consideration of the effect that will have on the patient, the medical team, and the mission overall, in keeping with ethics guidance on the exercise of conscience.

Sponsors of short-term medical service trips should:

- (d) Ensure that resources needed to meet the defined goals of the trip will be in place, particularly resources that cannot be assured locally.
- (e) Proactively define appropriate roles and permissible range of practice for members of the volunteer team, including the training, experience, and oversight of team members required to provide acceptable safe, high-quality care in the host setting. Team members should practice only within the limits of their training and skills in keeping with the professional standards of the sponsor's country.
- (f) Put in place a mechanism to collect data on success in meeting collaboratively defined goals for the trip in keeping with recognized standards for the conduct of health services research and quality improvement activities in the sponsor's country.

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2. AMENDMENTS TO OPINIONS 1.2.11, "ETHICAL INNOVATION IN MEDICAL PRACTICE"; 11.1.2, "PHYSICIAN STEWARDSHIP OF HEALTH CARE RESOURCES"; 11.2.1, "PROFESSIONALISM IN HEALTH CARE SYSTEMS"; AND 1.1.6, "QUALITY"

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

As the Council on Ethical and Judicial Affairs noted in its recent informational report on augmented intelligence (AI) in medicine:

AI systems represent the latest in a long history of innovations in medicine. Like many new technologies before them, AI-based innovations challenge how physicians practice and how they interact with patients at the same time that these innovations offer promises to promote medicine's Quadruple Aim of enhancing patient experience, improving population health, reducing cost, and improving the work life of health care professionals [1].

At the same time, several characteristics distinguish AI-enabled innovations from other innovations in medicine in important ways. The data-driven machine-learning algorithms that drive clinical AI systems have the potential to replicate bias in the data sets on which they are built and exacerbate inequities in quality of care and patient outcomes. The most powerful, and useful, models are "black boxes" that have the capacity to evolve outside of human observation and independent of human control. Moreover, the design, development, deployment, and oversight diffuse accountability over multiple stakeholders who have differing forms of expertise, understandings of professionalism, and diverging goals.

Published analyses of ethical challenges presented by AI in multiple domains have converged around a core set of goals [2,3,4]:

- · Protecting the privacy of data subjects and the confidentiality of personal information
- Ensuring that AI systems are safe for their intended use(s)
- Designing systems of accountability that are sensitive to the roles different stakeholders play in the design, deployment, performance, and outcomes of AI systems
- Maximizing the transparency and explainability of AI systems
- Promoting justice and fairness in the implementation and outcomes of AI systems
- Maintaining meaningful human control of AI technologies
- Accommodating human agency in AI-supported decision making/the use of AI

Realizing these goals for any AI system, in medicine or other domains, will be challenging. As the Gradient Institute notes in its report, Practical Challenge for Ethical AI, AI systems "possess no intrinsic moral awareness or social context with which to understand the consequences of their actions. To build ethical AI systems, designers must meet the technical challenge of explicitly integrating moral considerations into the objectives, data and constraints that govern how AI systems make decisions" [5]. Developers must devise mathematical expressions for concepts such as "fairness" and "justice" and specify acceptable balances among competing objectives that will enable an algorithm to approximate human moral reasoning. They must design systems in ways that will align the consequences of the system's actions with the ethical motivation for deploying the system. And oversight must meaningfully address "the problem of many hands" in ascribing responsibility with respect to AI systems [6].

GUIDANCE IN THE AMA CODE OF MEDICAL ETHICS

Policies adopted by the AMA House of Delegates address issues of thoughtful AI design (<u>H-480.940</u>, "Augmented Intelligence in Health Care") and matters of oversight, payment and coverage, and liability (<u>H-480.939</u>). Policy <u>H-295.857</u> addresses issues of AI in relation to medical education. AMA has further developed a framework for trustworthy AI in medicine that speaks broadly to the primacy of ethics, evidence, and equity as guiding considerations for the design and deployment of AI systems in health care and the interplay of responsibilities among multiple stakeholders [7].

The introduction of AI systems in medicine touches on multiple issues of ethics that are currently addressed in the AMA *Code of Medical Ethics*. These include quality of care, innovation in medical practice, stewardship of health care resources, and professionalism in health care systems, as well as privacy.

The *Code* grounds the professional ethical responsibilities of physicians in medicine's fundamental commitment of fidelity to patients. As <u>Opinion 1.1.1</u> notes:

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for patients' welfare.

From the perspective of professional ethics, securing this commitment should equally inform medicine's response to emerging AI-enabled tools for clinical care and health care operations.

Guidance in <u>Opinion 1.2.11</u>, "Ethical Innovation in Medical Practice," calls on individuals who design and deploy innovations to ensure that they uphold the commitment to fidelity by serving the goals of medicine as a priority. It directs innovators to ensure that their work is scientifically well grounded and prioritizes the interests of patients over the interests of other stakeholders. Opinion 1.2.11 further recognizes that ensuring ethical practice in the design and introduction of innovations does not, indeed cannot, rest with physicians alone; health care institutions and the profession have significant responsibilities to uphold medicine's defining commitment to patients.

<u>Opinion 11.2.1</u>, "Professionalism in Health Care Systems," defines the responsibilities of leaders in health care systems to promote physician professionalism and to ensure that mechanisms adopted to influence physician decision making are "designed in keeping with sound principles and solid scientific evidence," deployed fairly so that they "do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities." It similarly recognizes that institutional leaders should ensure that when these mechanisms are deployed they are monitored to identify and respond to the effects they have on patient care.

Individual physicians, and the institutions within in which they practice, have a responsibility to be prudent stewards of the shared societal resources entrusted to them, addressed in <u>Opinion 11.1.2</u>, "Physician Stewardship of Health Care Resources." Even as they prioritize the needs and welfare of their individual patients, physicians have a responsibility to promote public health and access to care. They fulfill that responsibility by choosing the course of action that will achieve the individual patient's goals for care in the least resource intensive way feasible.

Finally, as <u>Opinion 1.1.6</u>, "Quality," directs, all physicians share a responsibility for promoting and providing care that is "safe, effective, patient centered, timely, efficient, and equitable." This should be understood to include a responsibility to adopt AI systems that have been demonstrated to improve quality of care and patients' experience of care.

For the most part, individual physicians will be consumers of AI systems developed by others. As individual end users, physicians cannot reasonably be expected to have the requisite expertise or opportunity to evaluate AI systems. They must rely on their institutions, or the vendors from whom they purchase AI systems, to ensure that those systems are trustworthy.

Nonetheless, physicians do have an important role to play in promoting fair, responsible use of well-designed AI systems in keeping with responsibilities already delineated in the AMA *Code of Medical Ethics* noted above. Their

voice must be heard in helping to hold other stakeholders accountable for ensuring that AI systems, like other tools, support the goals and values that define the medical profession and to which individual practitioners are held. CEJA Report 4-JUN-21 outlines the kinds of assurances physicians should be able to expect from their institutions when a given AI system is proposed or implemented.

CONCLUSION

AI systems are already a fact of life in medicine and other domains; it would be naïve to imagine there will not be further rapid evolution of these technologies. Fidelity to patients requires that physicians recognize the ways in which AI systems can improve outcomes for their patients and the community and enhance their own practices. They should be willing to be reflective, critical consumers of well-designed AI systems, recognizing both the potential benefits and the potential downsides of using AI-enable tools to deliver clinical care or organize their practices.

The fact that existing guidance in the AMA *Code of Medical Ethics* already addresses fundamental issues of concern noted above, coupled with the pace and scope of continuing evolution of AI technologies, the council concludes that developing guidance specifically addressing augmented intelligence in health care is not the most effective response. Rather, the council believes that amending existing guidance to more clearly encompass AI will best serve physicians and the patients they care for.

As the council noted in CEJA Report 4-JUN-21, the implications of AI technologies, and more specifically, the exploitation of "big data" to drive improvements in health care, carries significant implications for patient privacy and confidentiality that warrant separate consideration. The council intends to address those implications separately in future deliberations.

RECOMMENDATION

In light of the foregoing, the Council on Ethical and Judicial Affairs recommend that Opinion 1.2.11, "Ethically Sound Innovation in Medical Practice"; Opinion 11.2.1, "Professionalism in Health Care Systems"; Opinion 11.1.2, "Physician Stewardship of Health Care Resources"; and Opinion 1.1.6, "Quality," be amended as follows and the remainder of this report be filed:

1. Opinion 1.2.11, Ethically Sound Innovation in Clinical Practice

Innovation in medicine can <u>span a wide</u> range <u>of activities</u>. From <u>It encompasses not only</u> improving an existing intervention, to introducing an innovation in one's own clinical practice for the first time, to using an existing intervention in a novel way, or translating knowledge from one clinical context into another <u>but also developing</u> <u>or implementing new technologies to enhance diagnosis</u>, treatment, and health care operations. Innovation shares features with both research and patient care, but it is distinct from both.

When physicians participate in developing and disseminating innovative practices, they act in accord with professional responsibilities to advance medical knowledge, improve quality of care, and promote the well-being of individual patients and the larger community. Similarly, these responsibilities are honored when physicians enhance their own practices by expanding the range of <u>tools</u>, techniques, and <u>or</u> interventions they offer to patients employ in providing care.

Individually, physicians who are involved in designing, developing, disseminating, or adopting innovative modalities should:

- (a) Innovate on the basis of sound scientific evidence and appropriate clinical expertise.
- (b) Seek input from colleagues or other medical professionals in advance or as early as possible in the course of innovation.
- (c) Design innovations so as to minimize risks to individual patients and maximize the likelihood of application and benefit for populations of patients.
- (d) Be sensitive to the cost implications of innovation.

(e) Be aware of influences that may drive the creation and adoption of innovative practices for reasons other than patient or public benefit.

When they offer existing innovative diagnostic or therapeutic services to individual patients, physicians must:

- (f) Base recommendations on patients' medical needs.
- (g) Refrain from offering such services until they have acquired appropriate knowledge and skills.
- (h) Recognize that in this context informed decision making requires the physician to disclose:
 - (i) how a recommended diagnostic or therapeutic service differs from the standard therapeutic approach if one exists;
 - (ii) why the physician is recommending the innovative modality;
 - (iii) what the known or anticipated risks, benefits, and burdens of the recommended therapy and alternatives are;
 - (iv) what experience the professional community in general and the physician individually has had to date with the innovative therapy;
 - (v) what conflicts of interest the physician may have with respect to the recommended therapy.
- (i) Discontinue any innovative therapies that are not benefiting the patient.
- (j) Be transparent and share findings from their use of innovative therapies with peers in some manner. To promote patient safety and quality, physicians should share both immediate or delayed positive and negative outcomes.

To promote responsible innovation, health care institutions and the medical profession should:

- (k) Ensure that innovative practices or technologies that are made available to physicians meet the highest standards for scientifically sound design and clinical value.
- (kl) Require that physicians who adopt innovative treatment or diagnostic techniques innovations into their practice have appropriate relevant knowledge and skills.
- (Im)Provide meaningful professional oversight of innovation in patient care.
- (mn)Encourage physician-innovators to collect and share information about the resources needed to implement their innovative therapies innovations safely, effectively, and equitably.
- 2. Opinion 11.2.1, Professionalism in Health Care Systems

Containing costs, promoting high-quality care for all patients, and sustaining physician professionalism are important goals. Models for financing and organizing the delivery of health care services often aim to promote patient safety and to improve quality and efficiency. However, they can also pose ethical challenges for physicians that could undermine the trust essential to patient-physician relationships.

Payment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians. They can encourage undertreatment and overtreatment, as well as dictate goals that are not individualized for the particular patient.

Structures that influence where and by whom care is delivered—such as accountable care organizations, group practices, health maintenance organizations, and other entities that may emerge in the future—can affect patients' choices, the patient-physician relationship, and physicians' relationships with fellow health care professionals.

Formularies, clinical practice guidelines, <u>decision support tools that rely on augmented intelligence</u>, and other tools <u>mechanisms</u> intended to influence decision making, may impinge on physicians' exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented.

Physicians in leadership positions within health care organizations and the profession should ensure that practices for financing and organizing the delivery of care:

- (a) <u>Ensure that decisions to implement practices or tools for organizing the delivery of care</u> Aare transparent <u>and</u> reflect input from key stakeholders, including physicians and patients.
- (b) Reflect input from key stakeholders, including physicians and patients.
- (b) Recognize that over reliance on financial incentives or other tools to influence clinical decision making may undermine physician professionalism.
- (c) Ensure ethically acceptable incentives that <u>all such tools</u>:
 - (i) are designed in keeping with sound principles and solid scientific evidence.
 - a. Financial incentives should be based on appropriate comparison groups and cost data and adjusted to reflect complexity, case mix, and other factors that affect physician practice profiles.
 - b. Practice guidelines, formularies, and other similar tools should be based on best available evidence and developed in keeping with ethics guidance.
 - c. Clinical prediction models, decision support tools, and similar tools such as those that rely on AI technology must rest on the highest-quality data and be independently validated in relevantly similar populations of patients and care settings.
 - (ii) are implemented fairly and do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities;
 - (iii) are implemented in conjunction with the infrastructure and resources needed to support high-value care and physician professionalism;
 - (iv) mitigate possible conflicts between physicians' financial interests and patient interests by minimizing the financial impact of patient care decisions and the overall financial risk for individual physicians.
- (d) Encourage, rather than discourage, physicians (and others) to:
 - (i) provide care for patients with difficult to manage medical conditions;
 - (ii) practice at their full capacity, but not beyond.
- (e) Recognize physicians' primary obligation to their patients by enabling physicians to respond to the unique needs of individual patients and providing avenues for meaningful appeal and advocacy on behalf of patients.
- (f) Are Ensure that the use of financial incentives and other tools is routinely monitored to:
 - (i) identify and address adverse consequences;
 - (ii) identify and encourage dissemination of positive outcomes.
- All physicians should:
- (g) Hold physician-leaders accountable to meeting conditions for professionalism in health care systems.

- (k) Advocate for changes in health care payment and delivery models how the delivery of care is organized to promote access to high-quality care for all patients.
- 3. Opinion 11.1.2, Physician Stewardship of Health Care Resources

Physicians' primary ethical obligation is to promote the well-being of individual patients. Physicians also have a long-recognized obligation to patients in general to promote public health and access to care. This obligation requires physicians to be prudent stewards of the shared societal resources with which they are entrusted. Managing health care resources responsibly for the benefit of all patients is compatible with physicians' primary obligation to serve the interests of individual patients.

To fulfill their obligation to be prudent stewards of health care resources, physicians should:

- (a) Base recommendations and decisions on patients' medical needs.
- (b) Use scientifically grounded evidence to inform professional decisions when available.
- (c) Help patients articulate their health care goals and help patients and their families form realistic expectations about whether a particular intervention is likely to achieve those goals.
- (d) Endorse recommendations that offer reasonable likelihood of achieving the patient's health care goals.
- (e) <u>Use technologies that have been demonstrated to meaningfully improve clinical outcomes to C</u>choose the course of action that requires fewer resources when alternative courses of action offer similar likelihood and degree of anticipated benefit compared to anticipated harm for the individual patient but require different levels of resources.
- (f) Be transparent about alternatives, including disclosing when resource constraints play a role in decision making.
- (g) Participate in efforts to resolve persistent disagreement about whether a costly intervention is worthwhile, which may include consulting other physicians, an ethics committee, or other appropriate resource.

Physicians are in a unique position to affect health care spending. But individual physicians alone cannot and should not be expected to address the systemic challenges of wisely managing health care resources. Medicine as a profession must create conditions for practice that make it feasible for individual physicians to be prudent stewards by:

- (h) Encouraging health care administrators and organizations to make cost data transparent (including cost accounting methodologies) so that physicians can exercise well-informed stewardship.
- (i) <u>Advocating that health care organizations make available well-validated technologies to enhance diagnosis,</u> treatment planning, and prognosis and support equitable, prudent use of health care resources.
- (ij) Ensuring that physicians have the training they need to be informed about health care costs and how their decisions affect resource utilization and overall health care spending.
- (jk) Advocating for policy changes, such as medical liability reform, that promote professional judgment and address systemic barriers that impede responsible stewardship.
- 4. Opinion 1.1.6, Quality

As professionals dedicated to promoting the well-being of patients, physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable.

While responsibility for quality of care does not rest solely with physicians, their role is essential. Individually and collectively, physicians should actively engage in efforts to improve the quality of health care by:

- (a) Keeping current with best care practices and maintaining professional competence.
- (b) Holding themselves accountable to patients, families, and fellow health care professionals for communicating effectively and coordinating care appropriately.
- (c) <u>Using new technologies and innovations that have been demonstrated to improve patient outcomes and experience of care, in keeping with ethics guidance on innovation in clinical practice and stewardship of health care resources.</u>
- (ed) Monitoring the quality of care they deliver as individual practitioners—e.g., through personal case review and critical self-reflection, peer review, and use of other quality improvement tools.

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