REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 02-N-21

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| Subject: | 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" |
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| Referred to: | Reference Committee on Amendments to Constitution and Bylaws |

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

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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 (H-480.940, "Augmented Intelligence in Health Care") and matters of oversight, payment and coverage, and liability (H-480.939). Policy H-295.857 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 Opinion 1.1.1 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 Opinion 1.2.11, "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.

Opinion 11.2.1, "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 Opinion 11.1.2, "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 Opinion 1.1.6, "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 span a wide range of activities. ~~From~~ It encompasses not only 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 but also developing or implementing new technologies to enhance diagnosis, 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 tools, techniques, ~~and~~ or 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.

(~~k~~l) Require that physicians who adopt ~~innovative treatment or diagnostic techniques~~ innovations into their practice have ~~appropriate~~ relevant knowledge and skills.

(~~l~~m) Provide meaningful professional oversight of innovation in patient care.

(~~m~~n) 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, decision support tools that rely on augmented intelligence, and other ~~tools~~ mechanisms 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) Ensure that decisions to implement practices or tools for organizing the delivery of care ~~A~~are transparent and 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 all such tools:

(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) Use technologies that have been demonstrated to meaningfully improve clinical outcomes to ~~C~~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) Advocating that health care organizations make available well-validated technologies to enhance diagnosis, treatment planning, and prognosis and support equitable, prudent use of health care resources.

(~~i~~j) 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) 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.

(~~c~~d)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.

(Modify HOD/CEJA policy)

Fiscal Note: Less than $500

REFERENCES

1. American Medical Association, Council on Ethical and Judicial Affairs. *Report 4-JUN-21: Augmented Intelligence & the Ethics of Innovation in Medicine*. Available at [proceedings, JUN 21 special mtg, when posted]
2. Matheny M, Israni ST, Ahmed M, Whicher D, eds. *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril*. Washington, DC: National Academy of Medicine. Available at https://nam.edu/artificial-intelligence-special-publication/. Accessed April 12, 2021.
3. Fjeld J, Achten N, Hilligoss H, Nagy AC, Srikumar M. *Principled Artificial Intelligence: Mapping Consensus in Ethical and Rights-based Approaches to Principles for AI*. Berkman Klein Center for Internet & Society. Research Publication No. 2020-1 January 15, 2020. Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3518482. Accessed April 12, 2021.
4. High-Level Expert Group on Artificial Intelligence. *Ethics Guidelines for Trustworthy AI*. April 2019. Available at https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai. Accessed April 12, 2021.
5. Gradient Institute. *Practical Challenges for Ethical AI*. 2019. Available at https://gradientinstitute.org/docs/gradientinst-whitepaper.pdf. Accessed April 12, 2021.
6. Braun M, Hummel P, Beck S, Dabrock P. Primer on an ethics of AI-based decision support systems in the clinic. *J Med Ethics.* 2020;0:1–8.
7. Crigger EJ, Reinbold K, Hanson C, et al. Trustworthy augmented intelligence in health care. Under peer review, *Journal of Medical Systems*.