

AMA Code of Medical Ethics

1.2.11 Ethically Sound Innovation in Medical Practice

Innovation in medicine can span a wide range of activities. It encompasses not only improving an existing intervention, 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, or interventions they 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.
- (l) Require that physicians who adopt innovations into their practice have relevant knowledge and skills.
- (m) Provide meaningful professional oversight of innovation in patient care.
- (n) Encourage physician-innovators to collect and share information about the resources needed to implement their innovations safely, effectively, and equitably.

AMA Principles of Medical Ethics: V,VIII