

Ethically Sound Innovation in Medical Practice

Code of Medical Ethics Opinion 1.2.11

Innovation in medicine can range from 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. Innovation shares features with both research and patient care, but 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 techniques and interventions they offer to patients.

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:

1. how a recommended diagnostic or therapeutic service differs from the standard therapeutic approach if one exists;
2. why the physician is recommending the innovative modality;
3. what the known or anticipated risks, benefits, and burdens of the recommended therapy and alternatives are;
4. what experience the professional community in general and the physician individually has had to date with the innovative therapy;
5. 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, the medical profession should:

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

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

(m) Encourage physician-innovators to collect and share information about the resources needed to implement their innovative therapies effectively.

AMA Principles of Medical Ethics: V, VIII

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