Prescribing medications responsibly in a pandemic

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Physicians are expected to prescribe drugs “based solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient” (Opinion 9.6.6, “Prescribing and Dispensing Drugs and Devices,” AMA Code of Medical Ethics). Under most circumstances, identifying and prescribing the appropriate medication to meet an individual patient’s needs is a relatively straightforward exercise. But in some circumstances, the decision can be clinically and ethically challenging.

Those circumstances include cases when approved therapies have proven ineffective for a patient with a serious medical condition, or when there are no approved therapies to treat the patient’s condition. In such cases, physicians may turn to off label prescribing of therapies approved for other conditions for their patient. The AMA Code of Medical Ethics addresses both scenarios in Opinion 1.2.11, “Ethically Sound Innovation in Medical Practice,” and Opinion 5.5, “Medically Ineffective Interventions.”

Opinion 1.2.11 provides ethics guidance for physicians who propose to use “an existing intervention in a novel way” or translate knowledge “from one clinical context to another.” Responsibly prescribing an approved medication for a novel, off label use requires that the physician do so:

- On the basis of sound scientific evidence and appropriate clinical expertise
- With input from colleagues or other medical professionals in advance or as early as possible in the course of innovation
- In ways that minimize the risks to individual patients and maximize the likelihood of application and benefit for populations of patients

Recommendation for off label use for an individual patient must be based on the patient’s medical need. Physicians must also explicitly seek the patient’s consent to the off-label use by disclosing:

- How the diagnostic or therapeutic service differs from the standard therapeutic approach (when there is one)
- Why the physician is recommending the innovative modality
- The known or anticipated risks, benefits and burdens of the recommended therapy and any alternatives
- Experience with the innovative use in the professional community in general and the
physician’s individual experience with the innovative use
Any conflicts of interest the physician may have with respect to the therapy

Having prescribed an innovative therapy, physicians must monitor and discontinue any therapy that is not benefitting the patient. To promote patient safety and quality of care, physicians should also share their findings with peers, including both positive and negative outcomes.

Physicians should never provide therapy—for approved uses or off label—that, in the physician’s best medical judgment, “cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals of care” (Opinion 5.5).

Additional ethics guidance in a pandemic

The AMA offers an overview of foundational guidance regarding medical ethics for health care professionals and institutions responding to the COVID-19 pandemic.