Innovation in Medical Practice

Position Statement

The American College of Obstetricians and Gynecologists and The American Congress of Obstetricians and Gynecologists

Innovation takes many forms: improving an existing intervention; introducing an innovation into one’s own clinical practice for the first time; using an existing intervention in a novel way; translating knowledge and skill from one clinical context into a new one.

Ethically sound innovation is based on good scientific evidence and principles: it is developed with input from peers; requires that innovators have—or acquire—appropriate knowledge, skill, and experience to minimize risks while maximizing benefits for patient populations; and is sensitive to cost implications as well as potential for conflicts of interest.

The American College of Obstetricians and Gynecologists and the American Congress of Obstetricians and Gynecologists (ACOG) recommend that when physicians adopt innovative diagnostic or therapeutic interventions, they should be transparent about:

- the status of the innovation in the profession
- their own experience with the innovation
- their rationale for offering the innovation

Informed consent thus must include not only a discussion about anticipated risks and benefits, and any conflicts of interest the physician may have with respect to the innovation, but also the physician’s own experience with the innovation.

Physicians should be aware of federal processes in place to approve new technology in the medical field. Specifically, physicians should understand that Section 510(k) of the Federal Food, Drug, and Cosmetic Act allows a device that is "substantially equivalent" to a device on the market prior to May 28, 1976 (a "predicate device") to be marketed and sold in the United States. These devices are generally referred to as "cleared" or "510(k) cleared" devices.1

A recent study notes that most medical devices recalled in the last five years for “serious health problems or death” had been previously cleared by the FDA using the 510(k) process.2

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Physicians must be aware as they use new devices that they may be exposing patients to potential risks not yet explored in randomized trials. The FDA maintains the Manufacturer and User Facility Device Experience (MAUDE) database\(^3\) to record adverse events; however, this system comes into play after devices are already being used in practice.

ACOG encourages hospitals and departments of obstetrics and gynecology to provide support for physicians who seek to innovate, ensuring ease in arranging appropriate proctorships. Furthermore, hospitals are encouraged to require a certain demonstrated level of experience with the innovation to obtain privileging. Finally, ACOG encourages physicians to maintain their skills through simulation practice and update of training when appropriate.

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