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## Ethics in surgical innovation: Vigorous discussion will foster future progress

**W**elcome to Cleveland Clinic. We are delighted to have you here, and I am sure this is going to be a very interesting and provocative meeting.

In 1873 Sir John Eric Erichsen, surgeon to Queen Victoria, wrote that “although methods of practice may be modified and varied, and even improved to some extent,” “the knife cannot always have fresh fields for conquest.” How wrong he was.

Surgical innovation has continued without a break from Erichsen’s day to ours. In 1873 only 2.5% of the population survived to age 65. Over the past 100 years, surgical innovation has helped to extend the average life expectancy to 76 years.

### ■ AN UNRULY TRADITION

Surgical innovation has happened largely without rules and by its own unruly tradition. In some ways, it is the last frontier in medicine. Today surgical innovation is arguably defined and barely regulated. Technical variation is the norm, and every patient is different. The boundary between taking an alternative approach and embarking on a novel human experimentation may be finely shaded. No surgical equivalent to the Food and Drug Administration monitors the operating room. Professional ethics and common sense guide routine intraoperative intervention.

Formal research projects are carried out in compliance with the institutional review board (IRB) and the usual ethical and regulatory standards for human subjects research. Between these two posts lies a large, vaguely defined field. That is where this symposium will be spending the majority of its time.

Surgical progress is problem-driven and rarely planned. It has often taken place under stress or in response to contingent need or opportunity.

In our own lifetimes we have seen the development

of cardiac surgery in a virtually rule-free environment. Surgery for coronary artery disease did not develop out of a surgical protocol but arose out of new knowledge of the disease mechanism and improvements in imaging, anesthesia, extracorporeal oxygenation, and a combination of gifted surgeons and experienced surgical teams. It was immediately accepted as therapy. There are similar examples in every surgical field.

Over the past 40 years only 10% to 20% of surgical techniques have undergone clinical trials. Transplant is a classic example. Cardiac transplant moved forward without clinical trials, and it is unlikely that clinical trials will ever be done. The laparoscopic revolution came about in the same way.

### ■ A REGULATORY BALANCING ACT

Regulation is necessary, but where and how much? In a recent speech here at Cleveland Clinic, Anne Mulcahy, chief executive officer of Xerox, said, “Most great things happen by accident and experimentation. The moment you try to streamline and keep everything captive to very focused and disciplined outcomes, you lose your ability to really invent.”

On the other hand, we cannot let surgery devolve into what a past president of the Canadian Medical Association called “a chaos of techniques devoid of moral purpose.”

Finding the right balance will be difficult. All of this makes this symposium on ethics in surgical innovation relevant, necessary, and likely to be of interest well beyond these rooms. The profession of surgery has everything to gain from a frank discussion of the issues surrounding innovation. A solid grasp of ethics will improve our practice, protect our patients, and foster progress and innovation as we go forward.

You have a wonderful opportunity to discuss with some of the finest innovators in surgery—who are here in this room—the ethical and moral dilemmas of innovation. We cannot, on the one hand, proceed completely without plan; on the other hand, we cannot regulate innovation out of existence. In the end, it is about our patients, and their interest has to be placed first.

Thank you for joining us. I am sure you are going to have an excellent symposium.

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Dr. Cosgrove is Chief Executive Officer and President of Cleveland Clinic and former Chairman of its Department of Thoracic and Cardiovascular Surgery.

Dr. Cosgrove reported that he has no financial interests or relationships that pose a potential conflict of interest with this article.

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