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Innovation in surgical technology and techniques: Challenges and ethical issues

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ABSTRACT

The pace of medical innovation continues to increase. The deployment of new technologies in surgery creates many ethical challenges including how to determine safety of the technology, what is the timing and process for deployment of a new technology, how are patients informed before undergoing a new technology or technique, how are the outcomes of a new technology evaluated and how are the responsibilities of individual patients and society at large balanced. Ethical considerations relevant to the implementation of ECMO and robotic surgery are explored to further discussion of how we can optimize the delicate balance between innovation and regulation.

Introduction

Robert E. Gross burst onto the stage of pediatric surgery worldwide when he successfully ligated a patent ductus arteriosis in a 7-year-old girl on August 26, 1938. He was then Chief Resident in Surgery at Children's under William E. Ladd, the Surgeon in Chief. Gross had carefully planned this bold operation by practicing it in the postmortem room and animal laboratory. He did it when Ladd was on summer vacation. Ladd never forgave Gross for that surgical coup. Gross was certain Ladd would not have allowed him to do it if he had been in town. This bold adventure was the opening wedge for surgical correction of congenital cardiac malformations. Gross commented that if she had not done well, he would likely be a farmer somewhere in New England. By the time of his retirement, more than 1400 PDA's had been divided by Gross and his residents.[1]

Today much is the same, innovations in the way surgeries are performed often occur with little or no advance oversight. If supervision is present, it is most likely done by hospital based medical-credentialing or peer review staff, who aim to assure that physicians are sufficiently skilled to perform a particular surgery at that hospital, or by the FDA if there is an investigational device involved, for the FDA tries to assure that surgical devices are safe and effective for their intended use. However, medical staffs do not often ask surgeons to be re-credentialed when they alter a surgery they have privileges to perform. Since completion of the first laparoscopic cholecystectomy[2] in 1985 there is a trend for taking well-established open procedures and performing them laparosocpically. This often involves a steep learning curve for the surgeon, with increased potential risk to the patient. Additionally, the FDA does not regulate the manner in which surgeons use approved surgical devices. This means that, in a practice akin to off-label drug use, surgeons can use approved devices in novel ways without FDA oversight. More than other kinds of medical practice, innovative surgical techniques raise the issue of the variation in skill levels among physicians and the impact that has on deciding whether innovation should be deployed as surgical practice or research. Surgeons can find themselves in the grey area that exists between what is defined as medical practice with little oversight and research which is subject to extensive controls. Surgical innovation raises many ethical dilemmas that affect patients, medical practitioners, the medical profession, and society at large raising the following questions: (1) How is the safety of a new technology or technique guaranteed? (2) What are the principles used by hospitals to responsibly deploy a new technology or technique? (3) How is informed patient consent obtained before undergoing a new technology or technique? (4) How are conflicts of interest that could prejudice the physician's judgment managed? (5) How are surgeons trained and credentialed in a new technology or technique? (6) How are the outcomes of a new technology or technique tracked, evaluated, and reported? (7) How are the responsibilities to individual patients and society at large balanced? To further explore these ethical questions innovations in Extra Corporeal Membrane

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Table 1
The principles incorporated into the Nuremberg Code and the report from the Belmont Committee regarding ethical and appropriate treatment of human subjects in medical research.

Nuremberg Code	
1	The voluntary consent of the human subject is essential.
2	The experiment should be necessary and such as to yield fruitful results for the good of society.
3	The experiment should be so designed and based on the results of animal experimentation and underlying knowledge such that the anticipated results justify the performance of the experiment.
4	The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5	No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur.
6	The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7	Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8	The experiment should be conducted only by scientifically qualified persons and with the highest degree of skill and care.
9	During the course of the experiment, the human subject should be at liberty to bring the experiment to an end.
10	During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage if he has probable cause to believe that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
Belmont Committee	
1	Respect for persons suggests that individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection.
2	Beneficence notes that persons should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.
3	Justice indicates that the benefits and burdens of research should be "fair in distribution."

Oxygenation (ECMO) and robotic surgery will be reviewed to illustrate some of the challenges in the deployment of new surgical technology and hopefully further the discussion of how we can optimize the delicate balance between innovation and regulation.

Surgical and device innovation, the Common Rule, and the FDA

Following the Nuremberg trial of Nazi doctors involved in human experimentation, the 1947 Nuremberg Code defined 10 points outlining legitimate and ethical medical research (Table 1).[3]

The Tuskegee syphilis experiment, in which impoverished, African-American men with syphilis were studied without treatment from 1932 to 1972, led to the Belmont Report in 1978 and the Code of Federal Regulations Title 45, Part 46: Protection of Human Subjects in 1991.[4] (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) Otherwise known as the Common Rule, 45 CFR part 46 details and implements the concepts of protection of human subjects in research and the development of institutional review boards (IRB). (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) Thus, human subjects in research are protected by a system which ensures that the doctrines outlined in the Nuremberg Code and Belmont Report are maintained.

Innovation is integral to the care of surgical patients.[5] The surgeon must constantly alter, amend, and combine standard techniques in the care of biologically unique clinical situations. This "surgical practice" adaptation is an accepted aspect of the specialty and one which is necessary to provide excellent patient care.[6] While minor variations are considered standard care, when does an innovation become research and "experimentation"? The Belmont Report defines practice as, "…interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success." (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) In contrast, research, "…designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective." The Belmont report goes on to say, specifically, that, "When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental,' in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective." Thus, at one end of the spectrum of surgical innovation is "practice," while at the other end is "research." In between is a "grey" zone into which major innovations my fall; major innovations which may present significant advances for patients and society, but in which substantial trial and error as well as risk to the individual patient may exist.[6]

The Food and Drug Administration (FDA) regulates devices under the authority first established by Congress in 1938.[7] In 1976, following several amendments to the Act that authorized this empowerment, FDA's authority was extended to regulate and ensure the safety and effectiveness of all medical devices sold in the United States. Subsequently, devices have been classified on the basis of the risk of illness or injury should device failure occur: the greater the risk, the higher the classification and the more stringent the requirements to demonstrate quality, safety, efficacy, and reliability (Table 2). The classifications and requirements are based on the 1976 Amendments to the Food, Drug, and Cosmetics Act and the Safe Medical Devices Act (SMDA) of 1990 followed by the 1997 Food and Drug Administration Modernization Act

Table 2
Classes of devices intended for human use based on the regulations from the amended Food, Drug, and Cosmetic Act which describe device classification. The entire FD&C act may be seen at http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm.

A	Class I, general controls—A device for which there is reasonable assurance of safety and effectiveness or which is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury.
B	Class II, special controls—A device which cannot be classified as a class I device. A device that is purported or represented to be for a use in supporting or sustaining human life.
C	Class III, premarket approval—A device which cannot be classified as a Class I or II device or is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.