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Ethical Issues in Cardiac Surgery

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Abstract

While ethical behavior has always been part of cardiac surgical practice, ethical deliberation has only recently become an important component of cardiac surgical practice. Issues such as informed consent, conflict of interest, and professional self-regulation, among many others, have increasingly attracted the attention of cardiac surgeons. This review covers several broad topics of interest to cardiac surgeons and cardiologists, and treats several other topics more briefly. There is much uncertainty about what the future holds for cardiac surgical practice, research, and culture, and we discuss the background of ethical issues to serve as a platform for envisioning what is to come.

Keywords

Cardiac Surgery; Ethics; Congenital Heart Disease; Informed Consent; Professionalism; Conflict of Interest; Patient-Physician Relationship; Clinical Equipoise; Dead Donor Rule; Tobacco

Introduction

Ethical behavior has always been part of cardiac surgical practice, but ethical deliberation has only recently become an important component of cardiac surgical practice [1]. Essential qualities for cardiothoracic surgeons are a strong fund of knowledge, well-honed clinical judgment, superior manual dexterity, courage, and self confidence, all of which are often taught explicitly and by example in training programs. Judgment regarding the ethical challenges that surgeons frequently encounter in practice, however, is seldom taught explicitly, but is conveyed to students and residents by example of attending surgeons dealing with such issues [2]. A concerted effort has been made to introduce ethical issues into cardiac surgery discourse in meetings and publications by the Ethics Forum of the Society of Thoracic Surgeons (STS) and American Association for Thoracic Surgery (AATS). In the last 12 years, the Ethics Forum has presented 38 programs at cardiac surgical meetings [101] and has published over 200 papers on ethical topics in cardiac, vascular, and general surgery journals [102].

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Recent scandals in clinical research have led to increased emphasis on ethics in research involving human subjects [3]. Both the Annals of Thoracic Surgery (ATS) and the Journal of Thoracic and Cardiovascular Surgery (JTCVS) subscribe to the guidelines of the International Committee of Medical Journal Editors, which stipulate that publication of research involving human subjects requires assurances that “the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration [103].” Ethical deliberation is relevant and important to both clinical practice and clinical research in cardiac surgery.

We will address recent discussions of the ethics of cardiac surgery in several general categories, such as informed consent, professional self regulation, research and innovation, conflicts of interest, and cardiac surgery as a business. We will also describe several more focused ethical controversies, such as clinical equipoise in design of clinical investigations, the dead donor rule in organ donation, honesty in dealing with insurance companies, and certain end-of-life issues.

Informed Consent

Paternalism in medical decision making—the doctor-knows-best viewpoint—dominated medical ethics since the time of Hippocrates nearly unchanged until the patient's rights movement in the late 1960s and 1970s. Consent was not unknown, however; for example, ancient Egyptian, Greek and Roman documents indicate that in some cases, the physician's intervention had to be approved by the patient. Plato (law IV) described problems, procedures, and modes of providing information that are similar to principles underlying contemporary formulations of informed consent [4]. In the Hippocratic tradition, the relationship between physicians and patients was informed by two clear requirements: the professional obligation of the physician to do what is best for the patient and the obligation of the patient to accept (originally, without question) the patient's decisions and intervention, though deception in the interest of protecting the patient (and the physician as well) was implicit in patient care [5].

The principle that grounds consent in the context of medical care is respect for patients' autonomy—patients' power to make their own decisions about how their bodies will be used and to act on those decisions [6]. Consent is the major manifestation of respect for autonomy. Thus, a cardiothoracic surgeon may not touch or treat another person without his consent, provided that the person has the capacity to make medical decisions and that decisions are made voluntarily, that is, without coercion or undue pressure. Physicians also have the right of autonomous decision making, however, so the contemporary physician-patient relationship can be described neither as “medical paternalism” (as in the Hippocratic tradition) nor as “patient sovereignty”, but as “shared decision-making,” in which the patient and the surgeon both play important roles in decision making [6].

Elements of informed consent

An important ethical problem in cardiac surgery, as in most other areas of medicine, is widespread misunderstanding or misuse of the informed consent process. The commonly used term “consenting the patient” (especially by house officers) by obtaining the signature implies that the patient has already agreed to the intended procedure, and that the signature on a piece of paper is the consent. But a signature is not consent, so the practice of routine “consenting” and its underlying idea is simply wrong—informed consent is not a document but is a process that we now describe.

Three sets of elements characterize informed consent: preconditions (capacity and voluntariness), information (disclosure and recommendations), and consent (decision and authorization) [7].

Preconditions for informed consent are the capacity to understand information and make decisions and the ability to make decisions voluntarily. *Capacity* to make decisions is not well-defined, either ethically or legally, but in general, capacity refers to the specific capabilities of the patient in the context of the decision's gravity[8]. For example, in a cardiac surgery patient, a much lower level of capacity is required to consent to a thoracentesis than to cardiac valve replacement. Loss of capacity is not infrequent and is often not recognized, although several instruments are available to detect and measure it [9].

Voluntariness is present when a patient's choices are intentional and unaffected by coercion or undue influence [10]; it is not absolute, but is a matter of degree, reflecting the amount of control an individual has over his behavior [11]. Evaluating voluntariness has always been a subjective undertaking, but recently an objective measure of voluntariness has become available [10]. This could be helpful in the future in evaluating difficult questions of capacity, such as individuals with serious life threatening conditions who might not be emotionally capable of consenting voluntarily either to clinical interventions or to research participation because of their distraught state of mind, limited options, and their difficulty in constraining unrealistic hope [12]. Surgeons must avoid applying pressure on a patient to produce consent, such as over-emphasizing benefit, under-emphasizing risk, deceiving by misinformation or omission, and subtly suggesting that an operation might not be provided unless a patient agrees to certain conditions.

Informational elements include *disclosure* of the nature of the disease and reasonable options for treatment; the purpose, risks, benefits, and potential consequences of the recommended therapy and its alternatives; the probability of success; and the prognosis without treatment. The information provided need not be all-inclusive, but should include all information that is material to the required decision. State law determines how much information must be conveyed, so is variable. An early standard, now used in only a few states, is the "professional practice standard": a cardiac surgeon should disclose what other surgeons in the community would disclose under similar circumstances. The law of most states employs the "reasonable patient standard": surgeons should disclose information that a reasonable person would deem important in making a decision. The recently introduced "subjective standard" is not a standard of state law, but is ethically well grounded: the cardiothoracic surgeon should disclose information that this particular patient would need to understand in order to make an informed decision. Although this standard faithfully respects the patient's autonomous decision making, it is difficult to incorporate into practice because information must be tailored to each patient and it places a considerable burden on the physician to determine what the patient wants.

Recommendation of a specific plan is based on the surgeon's expertise, which is the very reason the patient sought his care, so surgeons should neither so narrowly conceive respect for the patient's autonomy that he shies away from making a recommendation, nor should they minimize alternative options in the belief that their recommendations will always be consistent with the patient's worldview or value system.

The patient's *understanding* of the disclosed information, in addition to the surgeon's recommendation and the alternative treatment options, can be determined by asking the patient to repeat back what he has been told, expecting not a literal rendering of the discussion but a demonstration of understanding the essential points. Understanding by a lay person depends on the surgeon's use of jargon-free language at a level consistent with the

patient's capacity to understand. Talking down to patients using language that only the surgeon comprehends is a major flaw of communication—unfortunately too frequent—that can be avoided by thoughtful consideration of the patient's capabilities.

Consent elements conclude the consent process: a *decision* that the patient makes reflects what the patient considers to be the best option based on the information provided, given the situation and his own belief/value system. The patient must also provide authorization to the surgeon or surgeons to carry out the chosen treatment, either orally for minor decisions or in writing for major decisions.

If a patient will not make an explicit choice and says something like, “You're the doctor, you decide what's best for me,” the surgeon should explore the patient's meaning to determine that it is truly what the patient wants (not, for example, a response arising from lack of understanding). If it is clear that the patient truly wants to transfer decision making, the surgeon should make a specific recommendation, because the patient's transfer of the decision is itself a decision that constitutes consent.

A patient's explicit consent is not required under certain circumstances, such as emergencies that threaten life or limb and mandates of law (e.g., newborn screening), and, rarely, therapeutic privilege, in which the cardiothoracic surgeons withholds information that he believes threatens the patient's wellbeing. This privilege should be exercised rarely, if ever, as it is dishonest and the deception risks the patient's loss of the trust in the surgeon, the medical profession, or the entire health care system [13]. It should also be recalled that consent is not a one-time decision but is a continuing process linked to the evolving nature of the treatment [14].

The preceding discussion is a brief overview of the ethical considerations underlying informed consent, but we emphasize that state law is highly variable and cardiothoracic surgeons should be familiar with the laws governing the informed consent process in their own states.

Surrogate/proxy decision making

Common ethical errors arise from surgeons' misunderstanding the role of substitute decision makers in cases of incapacitated patients [15]. Physicians do not ultimately determine therapies in caring for patients—final decisions always belong to patients or their surrogates/proxies. A written advance directive, such as a living will or health care durable power of attorney, makes first-person decisions when applicable. If an individual lacks capacity to choose among treatment options, surrogate (appointed under law) or proxy (appointed by the patient) decision makers take the patient's place in consenting or refusing therapeutic options. They are entitled to the same level of informed consent as the patient would have been, as described in the previous section. When a written advance directive does not exist, two standards guide surrogate/proxy decision making, depending on circumstances. The primary standard is *substituted judgment*, which requires the surrogate/proxy to choose options that the patient would have selected when previously capable. If the patient's preferences are not known, the *best interest* standard controls decision making. Here the surrogate/proxy must select the treatment pathway that maximizes the ratio of benefits (treatments that improve patient's health state or health or quality of life) to burdens (treatments that provide no measurable health benefits or reduce the patient's quality of life) [104].

When using substituted judgment, the evidentiary standard differs among the states: most use the lowest standard, “preponderance of evidence,” but some use the higher standard of “clear and convincing evidence,” a difference that was critical in the ethically and legally

landmark 1990 U.S. Supreme Court case of Nancy Beth Cruzan. The Cruzan case established that individuals, either personally or through agents, have the right to refuse life-sustaining treatment, and that hydration and nutrition are medical treatments that can be refused [104].

Parental consent must be obtained where a child does not have sufficient understanding and is under 16 years of age, but even when children do not have sufficient understanding to make a valid decision, they should be allowed the opportunity to “assent” to the operation, that is, they should be consulted and account taken of their feelings and their wishes [16].

Consent is not a one-time decision but a continuing process linked to the evolving condition of the patient. Postoperatively, appropriateness of treatment should be revisited regularly during a hospital course and readjusted in light of the patient's condition rather than blindly continuing to follow the original treatment plan using every available technology to treat complications—unfortunately, this occurs altogether too frequently in our experience [14].

Professional Self-Regulation

Professional self-regulation is an individual or collective process of oversight and restraint which highlights the professionalism observed by surgeons. Self-regulation reflects the ethical concept of responsibility for patient care which involves accountability for the scientific and clinical quality of that care. The medical profession's intention to regulate itself independently is best exemplified by the consistent incorporation of critical reviews such as routine morbidity and mortality conference by surgical services in general and cardiac surgical services in particular. Two additional examples provide evidence of professional self-regulation in cardiac surgery.

Association disciplinary programs

Several specialty societies have developed disciplinary programs to deal with ethical violations by their members. Among cardiothoracic surgical societies, the two national societies in the U.S., the AATS [105] and the STS [106], have published codes of ethics that are enforced by a disciplinary process in each organization. The STS, for example, has initiated over 20 actions against its members for ethics violations over the last 5 years, and have meted out any of five sanctions against Society membership, ranging from a letter of admonition, letter of censure, probation, suspension of membership for a specified number of years, or expulsion from the organization.

Regionalization of care and the Bristol Royal Infirmary case

Prosecutors charged three surgeons affiliated with the Bristol Royal Infirmary with continuing to perform pediatric cardiac surgical procedures in 1988–1995 despite their knowing that their results were far worse than the national average (29 deaths after 53 cardiac operations, 55% mortality rate). Two of the three were charged as operating surgeons, the third was charged as an administrator who failed to take action after concerns were voiced by members of the medical staff. The case was sensational in the communications media because it concerned the deaths of children after heart operations. In addition, the case laid the foundation for the General Medical Council's policy of seeking to ensure that all members of the profession accept collective responsibility for maintaining professional standards and practicing within the limits of their competence [17].

Although the charges focused on cardiac surgeons, the decision to refer patients to them was made by others. Current surgical culture holds that outcomes are the product of team effort, so it seemed unfair to single out individuals for censure. Moreover, institutional shortcomings were acknowledged—conditions at the hospital were not conducive to

successful outcomes. These observations seem to argue for concentrating expertise in selected hospitals.

Regionalization of cardiac surgery care has been suggested as a way to improve outcomes. Recent evidence regarding the volume-outcome relationship for coronary artery bypass graft (CABG) does not demonstrate strong evidence for or against regionalization. Proponents of regionalization base their conclusions on data from large retrospective analyses that are prone to many biases and other flaws. Moreover, high volume programs may become complacent and aging high-volume surgeons may face diminishing skills and outdated techniques, leading eventually to worse outcomes. Conversely, low volume programs desire growth, so may strive vigorously to achieve excellence and demonstrate superior outcomes [18].

Surgical volume is merely a surrogate measure for the primary measure of interest—surgical outcomes. In order to make self regulation credible, outcome data for individual treatments are needed to allow cardiothoracic surgeons to compare their own results with those of colleagues performing the same procedures. Such benchmarking has been found useful in cardiothoracic surgery in the UK and the US with the introduction of national databases [19,20]. Truly useful evaluation of outcome data depends, however, on high-quality, risk-adjusted outcome measures that are being developed for national databases, but, although feasible, are still far from ideal [21].

Self-regulation of cardiac surgery is complex, and involves many levels of oversight aimed at guaranteeing the competence of the practicing cardiothoracic surgeons. Some activities that continue to be carried out with skill and rigor include accreditation of medical schools and training programs, licensure, and certification. These activities have performed well and have achieved their objectives efficiently [22]. Yet, problem areas remain: an important lesson to be drawn from the Bristol Royal Infirmary case is that cardiothoracic surgeons have a clearly defined responsibility to protect patients from being harmed by other cardiothoracic surgeons; many cardiothoracic surgeons seem not to be aware of this obligation [23].

Innovation and Research, Conflicts of Interest and Commitment

The distinction between innovation and research was first made in the Belmont Report and is further developed in the federal Common Rule [107]. Innovation is a non-validated change in therapy primarily aimed at benefiting an individual while research is a protocol-based study primarily aimed at gaining new knowledge. Each is associated with a different set of ethical issues.

Innovation

Cardiac surgery has a rich history of innovation related especially to development of new procedures and to incremental changes in existing procedures, exemplified by Norwood's creation of a surgical method to treat hypoplastic left heart syndrome in the 1980s and continuing innovations today [24]. Looked at through a contemporary lens, the biggest problem with innovation in cardiac surgery is lack of oversight—for the most part, innovations are undertaken by creative surgeons who believe they have a good idea that should work to benefit a patient. Regulation of innovation is opposed by many surgeons who fear that any controls would blunt creativity and stifle advances that often save lives and advance surgical science. Yet, an unexpectedly warm reception has been accorded the suggestion of one ethicist to create local or departmental "Innovation Review Committees" to oversee innovative practices that are so common in cardiac surgery, while avoiding the burdensome bureaucracies associated with research oversight [25].

Research

The Common Rule provides the most widely accepted definition of research, distinguishing it from innovation: “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” [107]. Much of the contemporary concern about research is associated with conflict of interest (COI), a concern we address in next section. Many other ethical issues are associated with research. The problem that led to current regulation of research was the use of human subjects without their consent. For example, the Common Rule in the U.S. is concerned with protection of human subjects from potential harm. It was preceded by the Nuremberg Code of 1947, which was promulgated consequent to the so-called Doctor's Trial of Nazi doctors, nurses and others who did medical research on unconsenting prisoners in concentration camps [26]. Motivated by Nazi research atrocities, the primary purpose of the Code and the Helsinki Declaration of 1964 [5] was to protect human subjects from harm.

During the conduct of research, other issues arise that relate to ensuring that the end result of the research is accurate and reliable, such as careful design of the research project, accuracy in the acquisition and management of data, preparation of research results for publication, and the process of publication [27]. Perhaps the most egregious of ethical violations is research misconduct, especially falsification and fabrication of data, because such activities undermine the foundation of research—the honest search for truth—and ultimately can result in harm to patients. Many famous cases of research misconduct have been documented, most recently Woo Suk Huang's infamous fabrication of data that led to sensational publicity after he falsely claimed in a scientific paper that he had cloned human embryonic stem cells in culture. His 2009 conviction for fraud and embezzlement was upheld by an appeals court in 2010 [108].

An interesting question related to unethically conducted investigations is whether such studies should be published. This question was resolved by the *Annals of Thoracic Surgery* with the decision to publish a study from the University of Beijing that had clear ethical violations: the journal would publish studies that were carried out unethically, provided the information was important and difficult or impossible to reproduce, and that the publication was accompanied by an editorial comment emphasizing the ethical violation, the importance of the information it contained, and a statement that the journal neither condones nor lightly publishes ethically compromised studies [28].

Conflict of interest

The term “conflict of interest” (COI) has been variously defined; a useful definition can be found in the Institute of Medicine's 2009 report on the subject: “A COI occurs when there is a divergence between an individual's private interests and his or her professional obligations.” [29] COIs are very frequent and unavoidable. The dilemma facing cardiothoracic surgeons is not so much how to avoid COIs completely, which is not possible, as it is how to manage and resolve them successfully [30]. Successful resolution is achieved by choosing to act in favor of the primary interest (in surgery, the patient's) rather than secondary interests (for example, personal gain).

In research, the greatest concern is with conflicts between the primary responsibility of surgeon-investigators to scientific honesty and objectivity and secondary obligations reflecting their personal interests [31]. Several scandals involving COIs in cardiac surgery have made national news, such as the Cleveland Clinic's ownership interest in AtriCure, a device manufacturer [32], and the death of a patient after his cardiac valve replacement, broadcast live to an audience gathered by the cardiothoracic surgeons who founded the valve manufacturing company [33]. A major mechanism for minimizing the effects of COIs in

research is requiring their disclosure at conferences and publications. The effectiveness of these requirements has been challenged, however, on grounds that when conflicts of interest are disclosed, people do not discount biased advice as much as they should, and disclosure can perversely increase bias because those giving advice can feel empowered to exaggerate their advice even more. For these reasons, disclosure may not diminish problems created by conflicts of interest and can even make them worse [34].

In clinical care, the greatest concern is with conflicts between cardiac surgeons' paramount responsibility to the interests of their patients and their own interests or those of others [35]. A great deal of attention has been focused on the relations between cardiothoracic surgeons and industry, in the realms of both clinical care and research. Senator Charles Grassley of Iowa has conducted investigations for the U.S. Senate, and introduced a bill several years ago that requires all companies to report payments to cardiothoracic surgeons on a public web site. The Physicians' Payments Sunshine Act was passed along with the Patient Protection and Accountability Act (PPACA) in 2010 [36]. Congress seems to believe that medical centers are not able to manage industry payments to cardiothoracic surgeons adequately, so it is possible that we will eventually have laws that completely cut the financial link between industry and cardiothoracic surgeons.

Other areas of concern with COIs are self-referral by cardiothoracic surgeons, cardiothoracic surgeons' risk sharing in health maintenance organizations (HMOs) and hospitals, hospital purchasing and bonding practices, industry sponsored research, and research on patients. Discussion of all these is beyond the scope of this review, but detailed discussion is available elsewhere [29].

Conflicts of obligation and commitment

COIs are related to two other kinds of conflicts [37]. A conflict of obligation occurs when a cardiothoracic surgeon has two responsibilities that are nearly equal—both are primary responsibilities—but only one can be discharged. An example that occurs frequently is when two patients need an ICU bed but only one is available. Such dilemmas are quite common and can be extremely difficult to resolve.

Conflicts of commitment are more closely related to COIs, in that the conflict is between two perfectly legitimate commitments of time and effort that are valued differently by different parties. For example, a cardiac surgeon might be under contract to a medical center and also work at a research institute; the medical center administration might believe that the surgeon is spending too much time doing research. Another conflict might involve non-professional commitments, such as caring for children or doing volunteer work for an outside organization. Such conflicts are generally handled through contractual stipulations.

More difficult conflicts of commitment may occur when important events occur in the surgeon's family that conflict with patient care responsibilities. The paramount clinical responsibility of cardiothoracic surgeons is to the interests of their patients [109], but this responsibility is not absolute, so when a conflict of commitment to both patients and family occurs, it can be particularly difficult to resolve. One ethically satisfactory resolution of such a conflict is for the surgeon to ensure satisfactory care for the patient by providing competent clinical coverage when he is not available because of important family and personal obligations.

Ethics and the Business Aspects of Cardiac Surgery

Dr. John Gregory two hundred years ago was among the first to identify the potential for conflict between the altruistic patient-centered facet of medicine and the business of

medicine as a means for financial gain [38]. He believed that putting economic self-interest before patients' interests would put their health and lives at increased risk. Adding practicality to Gregory's theories, current day cardiac surgical practice requires that a healthy balance be maintained. This requires constant awareness of one's ethical obligations. Cardiac surgeons who function at either extreme may suffer an unsuccessful and unsatisfying career: When a surgeon's primary interest is generating income, the quality of decision making and treatment may lead to inferior results. When an overzealous surgeon ignores his justly earned income, he may limit his ability to continue to offer consistent quality care to his patients.

Contemporary cardiac surgeons face diminishing payment for services, competition driven by institutional marketing, and complex billing requirements. They are confronted with choices to limit their practices to patients whose payers reimburse at a level that maintains an adequate income, which often means refusing to care for Medicaid and Medicare patients, thus placing the burden of diminished access to care on the poor and elderly. Alternatively, they may pursue an increasing volume of surgical cases to compensate for decreasing reimbursement, thus risking overtreatment. The ideal approach would be to continue to practice surgery based on science as well as clinical judgment and skills acquired through hard work over long years of training and practice. The problem for cardiac surgeons is how to deal with an imperfect world in which medical decisions have been driven increasingly by rule (insurance company) and regulation (government), and the burden of decreasing the high cost of health care has been increasingly placed on cardiothoracic surgeons' reimbursement—cardiac surgeons more than most. These factors are likely to be exacerbated as the provisions of the Affordable Care Act (ACA) are activated through 2014 [39].

To illustrate one aspect of this problem, a cardiac surgeon may be referred a terminally ill patient in whom the outcome is likely to be poor, such as a patient with severe distal left main artery stenosis who is debilitated with metastatic lung cancer and poor lung function and has a median projected survival of 6 months. His intractable angina is refractory to medical therapy and not amenable to percutaneous intervention. This case highlights the dilemma of balancing the patient's best option—a CABG procedure that would alleviate pain—against the cost of a high risk operation that might taint the surgeon's results. A cardiac surgeon's patient outcomes have never before been under more intense scrutiny. The cardiac surgeon is therefore faced with the unfortunate options of accepting a patient with predictably poor outcomes, which is likely to tarnish his outcomes report, referring the patient to another surgeon, often in a distant location that is inconvenient or inaccessible to the patient, or recommending no treatment, denying the patient otherwise reasonable beneficial treatment.

Ethical Controversies in Cardiac Surgery

Many ethical controversies have been reported or debated in the cardiac surgery literature in recent years. We describe a few of them in this section.

The Prisoner Dilemma

Prisoners have a special status in society; they are under confinement, having been deprived of their liberty, and are generally considered unworthy of the same considerations accorded ordinary citizens. Yet, they are constitutionally guaranteed medical care, and this requirement has led to disagreements over how much care is acceptable when they become sick enough to require organ transplantation.

In June 2011, a 36 year old drug trafficker was jailed for a repeat offense of trafficking in heroin just 12 days after serving 3 years of a 5 year sentence for a similar crime. He suffered a myocardial infarction while on remand and underwent insertion of a continuous flow left ventricular assist device (LVAD) as a bridge to transplantation. The judge suspended the minimum-5-year sentence on grounds of a markedly reduced life expectancy. The prisoner was placed under curfew with an electronic tag for six months. Anti-drug groups have argued that this would send a skewed message and set a dangerous precedent to criminals who would now believe that having a serious medical condition would be a means to a pardon and might encourage continued criminal activity. A spokesman for NHS Blood and Transplant said the prisoner's crimes should not influence his place on the transplant waiting list [110].

Cardiac transplantation and LVADs are expensive treatments for end stage heart disease. The severe shortage of donor hearts raise the question of whether a convicted felon should be allowed to undergo an expensive treatment that requires compliance with complex medication schedules as well as close follow-up for immunosuppression-infection surveillance. Should the felon receive a heart transplant, the donated heart would be denied to another patient whom many would consider more deserving, and who would die with a diseased heart. Moreover, prisons face progressively decreasing budgets, raising the question of whether hugely expensive treatments to treat felons are justified at all [40]. The broad underlying question has also been addressed in the cardiac surgery literature: what role, if any, should cardiac surgeons assign to social worth in considering indications for operation [41].

Clinical equipoise in research design

Randomized clinical trials are considered to be the gold standard for demonstrating effectiveness of competing medical treatments. Ethical justification for randomly assigning patients to arms of a study was provided by Benjamin Freedman in his classic paper on equipoise, in which he suggested that if “there is no consensus within the expert clinical community about the comparative merits of the alternatives to be tested”, then this uncertainty, which he named clinical equipoise, ethically justified exposing subjects to the alternative treatments [42].

An example of the successful use of clinical equipoise to resolve is the recently concluded Single Ventricle Reconstruction (SVR) Trial, which was a randomized clinical trial comparing two different shunts for the Norwood procedure to treat hypoplastic left heart syndrome: the standard modified Blalock-Taussig shunt and the newer right ventricle-to-pulmonary-artery shunt [43]. Although the RV-PA shunt was found to have a lower failure rate (death or heart transplant) at 12 months, there was a trend toward later ventricular dysfunction which may translate to worse long-term survival on further followup.

Recently, questions have been raised about the role and the relevance of clinical equipoise. For example, when the expert clinical community is identified, what is the minimum proportion of members who favor each alternate treatment? Moreover, expert opinion is fallible, often not supported by adequate evidence, and is based on the results of early phase trials with surrogate endpoints which often do not translate into clinically meaningful endpoints. Such questions are the basis of the suggestion that clinical equipoise is not a necessary condition for the ethical conduct of clinical trials [44].

Vigorous defense of the necessity for clinical equipoise as a condition for clinical trials has been offered, as well as arguments for modification rather than its abandonment. For example, equipoise should be more accurately defined as “a state of genuine agnosticism or conflict in the expert medical community about the preferred medically established

procedure for the condition under study.” This definition requires surgeon-researchers and members of IRBs to genuinely evaluate to what extent a proposed randomized clinical trial solves a state of agnosticism or a knowledge conflict in the expert medical community [45]. This debate lies at the heart of ethical justification for randomized human investigation and we await with interest its resolution.

Abandoning the dead donor rule

When organ transplantation became a reality over a half-century ago, the inadequate supply of organs threatened the survival of many patients with end-stage vital organ disease. Patients with severe brain damage who were about to die could be a source of additional organs, but there was fear that killing patients even if they were dying, was ethically and legally wrong. The solution came from an ad hoc committee at Harvard Medical School, chaired by Henry Beecher, which suggested revision of the definition of death in a way that would make some patients with devastating neurologic injury suitable for organ transplantation [46]. This idea was set in law by the Uniform Determination of Death Act, which established a second path to declaration of death in addition to the traditional cardiopulmonary path: death of the whole brain, including the brain stem, commonly known as brain death [47]. This avoided violating the unwritten but much discussed and faithfully observed dead donor rule (DDR), which has evolved from its original form—individuals must be declared dead before the removal of vital organs for transplantation—to its reformulation—removing vital organs must not cause death.

Patients who are declared brain dead are not really dead, some have argued, because some of the brain stem's homeostatic functions are still operational, e.g., temperature control and water and electrolyte balance. Moreover, some patients who have been pronounced brain dead have survived for many years with all bodily functions still working except consciousness and brain stem reflexes [48].

The DDR may be based on a flawed understanding of death, and by requiring organ donors to meet possibly flawed definitions before organ recovery, we deny patients and families of patients with devastating, irreversible neurologic injuries that do not meet the technical requirements of brain death the opportunity to donate organs [49]. For example, patients in a persistent vegetative state (PVS) who have advance directives not to be kept alive if ever they suffered PVS might have been enthusiastic potential organ donors before their brain injuries, and would want their organs used before cardiopulmonary death. Such patients do not meet brain death criteria (they have brain stem activity), so their healthy organs must be buried with them because of the DDR, thereby indirectly causing the deaths of as many as 8 patients in need of a vital organ that was not available. Yet, people often perceive legally living persons in irreversible coma or persistent vegetative state as dead, and others who believe such patients are alive would be willing nevertheless to procure organs from them [50]. There might be less public opposition to taking organs from vegetative patients than has been asserted by those who would like to conserve the DDR.

Scholars who oppose rigid adherence to the DDR have suggested different approaches to applying the above information. Some contend that the DDR is grounded in such flawed thinking that it should be abandoned [48]. Making exceptions to the DDR could permit organ recovery from patients in PVS or irreversible coma while still considering them to be alive but nearly dead. Alternatively, we could amend the definition of death to classify one or both groups as deceased, thus permitting procurement without violation of the dead donor rule [51]. These questions must be addressed as issues of public policy. Which if any of these approaches would be politically feasible is uncertain. Such a change could allow honest confrontation of the need for an increased organ supply by taking organs from patients who voluntarily consent, perhaps even demand, to be organ donors. We can also can

revert to a single definition of death that is easily understood without tortuous philosophical rationalizing: the irreversible absence of circulation [52].

Sleep Deprivation and Regulation of Surgeon Work Hours

Sleep deprivation has been shown to affect psychomotor performance negatively. Addressing this issue in the clinical setting provides a constant challenge, given competing needs for continuity of care and round-the-clock coverage of clinical services.

The Accreditation Council for Graduate Medical Education has addressed this problem by limiting residents' work hours with regulations that have undergone periodic revision [53]. Published studies of the effects of work hour regulations have shown mixed results, but generally demonstrate perceptions of improved life-style for residents, decline in quality of patient care, and no change in treatment outcomes between residents who are sleep-deprived (more than 16 hours on duty) compared with those who are not [54]. An investigation of the effects of sleep deprivation in thoracic surgery residents found that there was no adverse effect on patient outcomes after CABG [55].

No such regulations exist for practicing cardiac surgeons. Sleep physiologists identified this as an area of medicine that may be amenable to policies aimed at improving patient safety by reducing the adverse effects of sleep deprived surgeons [56]. They proposed that the surgeon be required to disclose to a preoperative patient lack of sleep before the operation and the risk of an increased complication rate. They also concluded that it is ethically incumbent on a sleep-deprived surgeon to offer postponement of the surgery or transfer of the operation to a colleague. The counterpoint to this is potential deterioration of professionalism from undermining of the deeply embedded surgical ethic of dedication to the care of individual patients. In an accompanying letter to the editor, officials of the American College of Surgeons contended that such mandated disclosure is unwarranted and that many stressors in life, such as marital discord, illness of children, and financial stress, may also affect clinical performance. What is needed, they said, is training surgeons to identify circumstances in which it would be reasonable to discuss with a patient cancellation or postponement of an operation [57].

A recent study evaluated the impact of sleep deprived attending surgeons on the outcome of patients undergoing CABG. They found that sleep deprivation did not affect the morbidity and mortality rates of patients undergoing CABG and they did not support the need for work hour restriction in attending surgeons [58]. Postponing cases routinely without evaluating the amount and acuity of sleep deprivation and the associated circumstances seems illogical because it has harmful effects on patients, their families, the surgeon and the hospital system. Surgeon discretion on a case-by-case basis may be the most rational approach and may cause the fewest adverse effects.

Honesty in dealing with third parties

Since antiquity, honesty in dealing with patients has not been considered a virtue. Deceiving a patient about his condition in order to protect him from harmful stress has been advocated since at least the time of Hippocrates: "Perform these duties commonly and adroitly, concealing most things from the patient while you are attending to him... revealing nothing of the patient's future or present condition" [59]. The term "therapeutic privilege" describes the practice of deceiving patients to protect them; it has been criticized for its dishonesty and threat of undermining the patient's trust in the physician and the profession [60]. In the contemporary era of bioethics, the emphasis has been on honesty in all relations, with patients as well as others. The ethical principle underlying this shift is respect for the

patient's autonomy: patients cannot make sound decisions about their health care unless they are in possession of truthful facts about their health status.

Being honest with patients is clearly stated in the AMA's Code of Medical Ethics: "It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients" [60]. In one specific aspect of health care, deception has been widely practiced and has achieved broad acceptance: misrepresentation of patient-related information in submissions to insurance companies. In one survey, the proportion of physicians who would support a colleague in deceiving a third-party payer was related to the perceived severity of the threat to the patient's health. The highest level of support for deception was 58% of surveyed physicians if the service were CABG. The lowest was for cosmetic surgery, at 3% [61]. This study and others support the view that physicians deceive insurance companies in their role as advocates for the patients.

Most ethicists advocate honesty in dealing with everyone, including insurance companies. The reason this advice is frequently ignored, according to one observer, is that insurance companies are perceived as the enemy of patient care, and since deceiving enemies is perfectly acceptable, the same can be done to insurance companies [62]. Yet this logic is faulty. The insurance company is not the enemy because patients or their agents, usually their employers, choose a health insurance policy based in part on higher or lower cost, and lower premiums are generally associated with fewer benefits. When an insurance company denies payment on grounds that it is not covered, the patient is getting what he or his agent has paid for. If a patient or his agent does not like the policies of the insurance company, he can take his business to a more reliable company. Deceiving the insurance company, however, does not rectify the problem the company has created for the patient.

Benefits and harms result from this practice. In the short term, benefits accrue to the patient, who gets the procedure that would not have been covered, and the surgeon is paid for services he otherwise would not perform. There are few obvious harms. In the long-term, however, the balance of benefits and harms changes. The patient benefits by being appropriately cared for and the surgeon is financially better off. The harms, however, are considerable. If the surgeon's deception is detected, he is vulnerable to the charge of fraud and its harsh legal consequences. Moreover, repeated deceptions of this kind undermine the character of the surgeon, for whom deceptive practices can spread beyond lying to insurance companies. Deception also undermines the trust the patient may have felt for the surgeon, because, if he lies to the insurance company, how can the patient know that she herself will not also be deceived? Broader harms also may occur, in that deceptions may conceal flaws in the health care system rather than exposing them so they can be dealt with openly. Surgeons should not deceive insurance companies, even for seemingly virtuous purposes.

Anti-smoking laws

Thoracic surgeons as a group strongly endorse laws that restrict smoking in public places. The rationale for this seems obvious: thoracic surgeons have personal experiences with the pathology associated with smoking, therefore, because it is so dangerous to health, it should be prohibited or at least closely regulated. The arguments in favor of laws prohibiting smoking in public places, however, are not based on evidence of direct harm to the health of smokers. They are mostly based on the public-health consideration of danger to others from secondhand smoke. The facts are that secondhand smoke causes disease and death in children and non-smoking adults, and that there is no risk-free level of exposure to secondhand smoke. While U.S. law spells out what society owes to individuals, international documents indicate what individuals owe to society, including respecting the right to a healthy environment, a fundamental human right that creates the imperative for laws that reduce secondhand smoke exposure.

The counterarguments to the anti-smoking position can be persuasive. The long-standing American concern for protection of individual liberty and self-determination requires that overriding these protections must show clear increases in personal risk above the level of background health risks of public places. The characterization of secondhand smoke as “involuntary” exposure in bars and restaurants is misdirected, because clients of such establishments choose to be there voluntarily, and could have chosen other places where smoking is not permitted if they wished to be free of exposure to secondhand smoke. Moreover, bars and restaurants generally are not public places, but are private businesses that cater to those who enter them voluntarily. It seems clear that those who frequent bars and restaurants that allow smoking choose to enjoy the company, inexpensive drinks, and other benefits such establishments afford, rather than places that pose fewer smoking-related risks. We allow people to engage freely in activities that pose much greater risks than secondhand smoke, such as joining a police force, parachuting out of airplanes, hang gliding, engaging in promiscuous sex, and body piercing. There is no rational distinction between such activities and exposure to secondhand smoke [63].

This is a complex topic and admits to sophisticated argumentation on both sides. The opinions of many cardiothoracic surgeons to the contrary, however, justification for laws banning smoking in public places is not self-evident.

Conclusion

Deliberation on ethical issues among surgeons in general [64] and cardiothoracic surgeons in particular[1] has gained prominence in recent years and is gradually becoming part of the curriculum in many training programs. A recent review found that although incorporating ethics into surgical training is valuable, the methods and content are not yet standardized [65].

The impact of ethics education specifically in cardiothoracic surgery has been investigated recently and found that surgeons who attended ethics educational sessions at national meetings experienced substantially increased understanding of complex ethical issues, and noted effects of that exposure on their clinical practices [1]. Ethics topics have not been included in the weekly curriculum for resident education established by the Thoracic Surgical Directors Association(TSDA)[111]. Furthermore, knowledge or understanding of ethical processes involving cardiac surgery is not a mandatory requirement and not formally recommended during the qualification or certification process.

A need currently exists for a fund of knowledge and judgment about ethical challenges that will be encountered in the daily practice of cardiac surgery. The Ethics Forum, a group that was formed in 1999 to develop ethics-related events and educational materials has helped to encourage awareness of ethical issues and ethics education for cardiothoracic surgeons as evidenced by substantial numbers of publications and educational events regarding ethics in the last decade. In spite of the new opportunities created by the Ethics Forum, there have been no formal requirements for training of cardiac surgery residents. This need is more evident now than ever and is reflected in a recent poll in which a majority of respondents agreed that inclusion of ethical understanding be made a requirement of the cardiothoracic surgery certification process [1].

Despite the documented need, cardiac surgical training has not yet formally included ethics. There is a currently ongoing effort to include ethics questions in the American Board of Thoracic Surgery examination; if this comes to pass, it will create an incentive to introduce more education in ethical deliberation into training programs and continuing medical education. Increased public awareness and focus on health care, health care reform, and

fiduciary responsibilities of surgeons are likely to provide additional impetus for recognition of ethics as a fundamentally important part of cardiac surgical practice.

Future perspectives

Albert Einstein is quoted as having said, “I never think of the future - it comes soon enough.” [66] We prefer to think about the future the same way, but have been tasked with making predictions about the direction that some of the ethical issues we have discussed will take in the next 5–10 years. Nearly all the topics we have discussed will continue to be problems in the future, in our opinion.

Respect for self-determination is deeply embedded in American culture and law, so the requirements of informed consent are unlikely to weaken. Rather, they are likely to be strengthened, if not through statute then through malpractice litigation, in which informed consent plays a large role and for which there seems little prospect of effective reform anytime soon.

Professional self-regulation will continue to be an issue as the locus of control over medical decision-making drifts farther from the patient-surgeon dyad into the offices of the new agencies currently being created under the ACA. Disciplinary policies are likely to be more widely adopted and utilized by specialty societies.

Biomedical research is likely to come under greater regulatory control. The National Institutes of Health has recently requested commentary on a proposed revision of the Common Rule, which regulates research and research ethics. It seems likely to be a few years before the final rule is realized, and its contents cannot be predicted at this time [112].

Focus on conflicts of interest in the relations between industry and cardiothoracic surgeons, as well as their specialty societies, will continue to intensify as government scrutiny of those relations increases consequent to the Physicians Payments Sunshine Act of 2010. The current regulatory atmosphere seems headed toward ever-increasing restrictions on financial interactions between physicians and industry, perhaps going as far as complete prohibition.

Issues related to organ donation, especially just allocation, will not diminish because the gap between number of patients on transplant waiting lists and available number of organs will continue to grow, as it has virtually unabated for 25 years. Insistence on an altruistic-only motivation to donate will probably continue to predominate, preventing adoption of strategies such as financial incentives for organ donors.

Despite conflicting evidence of effects on clinical care, mandatory work schedules for residents are likely to continue to be made more rigid. Of greater concern are the indications of movement toward imposition of mandatory work hour limits on practicing surgeons. These efforts are likely to intensify the changes in surgical culture that are already evident: a clock-watching mentality is replacing time-independent dedication to patient care, resulting in fragmented, lower quality patient care, an effect that will be greater in surgery—where repetition and case volume are closely related to enhancement of technical ability—than in non surgical specialties.

Honesty in dealing with third parties will continue to be an issue, and enforcement of anti-fraud policies and laws is likely to grow more intense as governmental funding progressively increases over the next few years as various parts of the ACA come on line.

Public reporting of cardiac surgical outcomes began in the 1990s in New York and Pennsylvania, and recently appeared in Consumer Reports. This practice is likely to grow

and the growing pains will include inadequate risk adjustment, leading to undeserved benefits and harms to different groups of cardiothoracic surgeons and heart care centers. Risk adjustment can be done well or poorly—the hope is that it will be done better as time goes by [81].¹

Antismoking laws have expanded beyond local ordinances to broader jurisdictions. The spread of such laws will continue, perhaps even becoming part of federal law at some point in the future.

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References

1. D'Amico TA, McKneally MF, Sade RM. Ethics in cardiothoracic surgery: a survey of surgeons' views. *Ann. Thorac. Surg.* 2010; 90(1):11–13. [PubMed: 20609739]
2. Sade RM, Williams T, Haney C, Perlman D, Stroud M. The ethics gap in surgery. *Ann. Thorac. Surg.* 2000; 69(2):326–329. [PubMed: 10735656]
3. Block M, Khitin L, Sade R. Ethical process in human research published in thoracic surgery journals. *Ann. Thorac. Surg.* 2006; 82:6–12. [PubMed: 16798178]
4. Plato. Translated into English with Introduction, Analysis, Marginal Analysis and Index. 3rd Ed.. Oxford University Press at the Clarendon Press; London: 1888. *The Republic of Plato*.
5. Sade RM. Deceiving insurance companies: new expression of an ancient tradition. *Ann. Thorac. Surg.* 2001; 72(5):1449–1453. [PubMed: 11722024]
6. Kon AA. The shared decision-making continuum. *JAMA.* 2010; 304(8):903–904. [PubMed: 20736477] * Kon provides an excellent discussion of what shared decision making is and the many forms it can take.
7. Boyle, RJ. The process of informed consent. In: Fletcher, JC.; Lombardo, PA.; Marshall, MF.; Miller, FG., editors. *Introduction to Clinical Ethics*. 2nd Ed.. University Publishing Group; Frederick, MD: 1997. p. 89-109.* Fletcher's *Introduction to Clinical Ethics* has several excellent discussion of the foundation of bedside ethics that are still current and pertinent.
8. Boyle, RJ. Determining patients' capacity to share in decision making. In: Fletcher, JC.; Lombardo, PA.; Marshall, MF.; Miller, FG., editors. *Introduction to Clinical Ethics*. 2nd Ed.. University Publishing Group; Frederick, MD: 1997. p. 71-88.
9. Sessums LL, Zembruska H, Jackson JL. Does this patient have medical decision-making capacity? *JAMA.* 2011; 306(4):420–427. [PubMed: 21791691]
10. Miller VA, Ittenbach RF, Harris D, et al. The Decision Making Control Instrument to assess voluntary consent. *Med Decis Making.* 2011
11. Wall E. Voluntary Action. *Philosophia.* 2001; 28(1–4):127–136.
12. Minogue BP, Palmer-Fernandez G, Udell L, Waller BN. Individual autonomy and the doubleblind controlled experiment: the case of desperate volunteers. *J. Med. Philos.* 1995; 20(1):43–55. [PubMed: 7738458]
13. Council on Ethical and Judicial Affairs. Code of Medical Ethics of the American Medical Association. 2010–2011 Ed.. American Medical Association; Chicago: 2010. Opinion 8.082, Withholding information from patients; p. 269-270.
14. Hecker, S.; Sade, RM. Ethical issues in cardiothoracic surgery for the elderly. In: Katlic, MR., editor. *Cardiothoracic Surgery in the Elderly*. Springer; New York: 2011. p. 89-104.

15. Fletcher, JC. The decision to forego life-sustaining treatment when the patient is incapacitated. In: Fletcher, JC.; Lombardo, PA.; Marshall, MF.; Miller, FG., editors. *Introduction to Clinical Ethics*. 2nd Ed.. University Publishing Group; Frederick, MD: 1997. p. 71-88.
16. American Academy of Pediatrics Committee on Bioethics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics*. 1995; 95(2):314–317. [PubMed: 7838658]
17. Irvine D. The performance of doctors. II. Maintaining good practice, protecting patients from poor performance. *BMJ*. 1997; 314:1613–1615. [PubMed: 9186177]
18. Nallamothu BK, Eagle KA, Ferraris VA, Sade RM. Should coronary artery bypass grafting be regionalized? *Ann. Thorac. Surg.* 2005; 80(5):1572–1581. [PubMed: 16242420]
19. Warden J. Dobson criticises GMC. *BMJ*. 1998; 316:1925.
20. Edwards FH. Evolution of the Society of Thoracic Surgeons National Cardiac Surgery Database. *J Invasive Cardiol*. 1998; 10:485–488. [PubMed: 10762829] **The STS database is the most complete surgical database based on verified clinical data (rather than misleading and clinically inaccurate administrative data) in the world. Dr. Edwards was one of its creators and continues to be one of its major proponents.
21. Shahian DM, O'Brien SM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 3--valve plus coronary artery bypass grafting surgery. *Ann. Thorac. Surg.* 2009; 88(1 Suppl):S43–62. [PubMed: 19559824]
22. Cruess SR, Cruess RL. The medical profession and self-regulation: a current challenge. *Virtual Mentor*. 2005; 7(4)
23. Council on Ethical and Judicial Affairs. Code of Medical Ethics of the American Medical Association. 2010/2011 Ed.. American Medical Association; Chicago: 2010. Opinion 9.031, Reporting impaired, incompetent, or unethical colleagues; p. 321-323.
24. Zannini L, Borini I. State of the art of cardiac surgery in patients with congenital heart disease. *J. Cardiovasc. Med.* 2007; 8(1):3–6.
25. Morreim H, Mack MJ, Sade RM. Surgical innovation: too risky to remain unregulated? *Ann Thorac Surg*. 2006; 82(6):1957–65. [PubMed: 17133664] * Innovation is differentiated from research and a minimally intrusive method of overseeing innovation is described.
26. Annas, GJ.; Grodin, MA., editors. *The Nazi doctors and the Nuremberg Code: human rights in human experimentation*. Oxford University Press; New York: 1992. p. 2
27. Shamoo, AE.; Resnik, DB. *Responsible Conduct of Research*. 2nd Ed.. Oxford University Press; New York: 2009. Misconduct in research; p. 140-166. **This is the best available source of information about research ethics. It describes the philosophy underlying research ethics and has excellent practical discussions based on hypothetical and actual cases.
28. Sade RM. Publication of unethical research studies: the importance of informed consent. *Ann. Thorac. Surg.* 2003; 75:325–328. [PubMed: 12607632]
29. Lo, B.; Field, MJ., editors. *Institute of Medicine. Committee on Conflict of Interest in Medical Research, Education, and Practice*. National Academies Press; Washington, DC: 2009. What is a conflict of interest? Conflict of Interest in Medical Research, Education, and Practice; p. 45-48.
30. McKneally MF. Beyond disclosure: Managing conflicts of interest to strengthen trust in our profession. *J. Thorac. Cardiovasc. Surg.* 2007; 133:300–302. [PubMed: 17258551]
31. Resnik, D. *The Price of Truth: How money affects the norms of science*. Oxford University Press; New York: 2007.
32. Armstrong D. Delicate operation: how a famed hospital invests in device it uses and promotes. *Wall Street Journal*. Dec 12.2005 :A1.
33. Weintraub A, Barrett A. Medicine in conflict. *Businessweek*. Oct 23.2006 :76–87.
34. Cain DM, Loewenstein G, Moore DA. The dirt on coming clean: perverse effects of disclosing conflicts of interest. *J. Legal. Studies*. 2005; 34:1–25. * The authors provide an excellent review of the COI literature and some original data, all showing the danger in relying on disclosure of conflicts to mitigate their effects.
35. Council on Ethical and Judicial Affairs. Code of Medical Ethics of the American Medical Association. 2010–2011 Ed.. American Medical Association; Chicago: 2010. Principle VIII; p. lxxi-lxxv. ** The annotated Code of Medical Ethics is the most comprehensive examination of ethical issues for physicians available today. It is the standard for medical ethics most often used

- by judicial courts and licensure boards in the U.S., and has comprehensive references to ethics and legal literature.
36. Transparency reports and reporting of cardiothoracic surgeons ownership or investment interests. Social Security Act 1128G 42 U.S.C. § 1320a-7h. 2010
 37. Shamoo, AE.; Resnik, DB. *The Responsible Conduct of Research*. Oxford University Press; New York: 2009. Conflicts of Interest and Scientific Objectivity; p. 189-214.
 38. McCullough LB. John Gregory's medical ethics and the reform of medical practice in eighteenth century Edinburgh. *J. R. Coll. Cardiothoracic surgeons Edinb.* 2006; 36(1):86–92.
 39. Keehan SP, Sisko AM, Truffer CJ, et al. National health spending projections through 2020: economic recovery and reform drive faster spending growth. *Health Aff. (Millwood)*. 2011; 30(8): 1594–1605. [PubMed: 21798885]
 40. Podger, PJ. Controversial heart transplant: inmate's operation at \$1 million cost to taxpayers angers many. *San Francisco Chronicle*: Feb 3. 2002
 41. DiMaio JM, Salerno TA, Bernstein R, Araujo K, Ricci M, Sade RM. Ethical obligation of surgeons to non-compliant patients: can a surgeon refuse to operate on an intravenous drug-abusing patient with recurrent aortic valve prosthesis infection? *Ann. Thorac. Surg.* 2009; 88(1):1–8. [PubMed: 19559179]
 42. Freedman B. Equipoise and the ethics of clinical research. *N. Engl. J. Med.* 1987; 317:141–145. [PubMed: 3600702] * This is the classic paper on clinical equipoise—Freedman coined the term in this article.
 43. Ohye RG, Sleeper LA, Mahony L, et al. Comparison of shunt types in the Norwood procedure for single-ventricle lesions. *N. Engl. J. Med.* 2010; 362(21):1980–1992. [PubMed: 20505177]
 44. Miller FG, Joffe S. Equipoise and the dilemma of randomized clinical trials. *N. Engl. J. Med.* 2011; 364(5):476–480. [PubMed: 21288100]
 45. van der Graaf R, van Delden JJ. Equipoise should be amended, not abandoned. *Clin. Trials*. 2011
 46. A definition of irreversible coma: report of the ad hoc committee of the Harvard medical school to examine the definition of brain death. *J.A.M.A.* 1968; 205:337–340.
 47. Guidelines for the determination of death. Report of the medical consultants on the diagnosis of death to the president's commission for the study of ethical problems in medicine and biomedical and behavioral research. *J.A.M.A.* 1981; 246(19):2184–2186. * This report established the rationale for using neurological criteria to determine death in addition to the traditional cardiopulmonary criteria, and was the basis of the Uniform Declaration of Death Act.
 48. Miller FG, Truog RD. Rethinking the ethics of vital organ donations. *Hastings Center Report*. 2008; 38(6):38–46. [PubMed: 19192716]
 49. Truog RD, Miller FG. The dead donor rule and organ transplantation. *N. Engl. J. Med.* 2008; 359(7):674–675. [PubMed: 18703469]
 50. Veatch RM. Transplanting hearts after death measured by cardiac criteria: the challenge to the dead donor rule. *J. Med. Philos.* 2010; 35(3):313–329. [PubMed: 20439354]
 51. Veatch RM. Abandon the dead donor rule or change the definition of death? *Kennedy Inst. Ethics J.* 2004; 14(3):261–276. [PubMed: 15497226]
 52. Sade RM. Brain death, cardiac death and the dead donor rule. *J. So. Carolina Med. Assoc.* 2011; 107:99–102.
 53. Nasca TJ, Day SH, Amis ES Jr. The new recommendations on duty hours from the ACGME task force. *N. Engl. J. Med.* 2010; 363(2):e3. [PubMed: 20573917]
 54. Yaghoubian A, Kaji AH, Putnam B, de Virgilio C. Trauma surgery performed by “sleep deprived” residents: are outcomes affected? *J. Surg. Educ.* 2010; 67(6):449–451. [PubMed: 21156307]
 55. Ellman PI, Kron IL, Alvis JS, et al. Acute sleep deprivation in the thoracic surgical resident does not affect operative outcomes. *Ann. Thorac. Surg.* 2005; 80:60–65. [PubMed: 15975341] * This study assesses the impact of sleep deprivation on patient outcomes and shows no adverse effects on patient outcomes related to sleep deprivation in the operating residents.
 56. Nurok M, Czeisler CA, Lehmann LS. Sleep deprivation, elective surgical procedures, and informed consent. *N. Engl. J. Med.* 2010; 363:2577–2579. [PubMed: 21190452]

57. Pellegrini CA, Britt LD, Hoyt DB. Sleep deprivation and elective surgery. *N. Engl. J. Med.* Dec 30; 2010 363(27):2672–3. [PubMed: 21190468]
58. Ellman PI, Law MG, Tache-Leon C, et al. Sleep deprivation does not affect operative results in cardiac surgery. *Ann. Thorac. Surg.* 2004; 78:906–911. [PubMed: 15337018]
59. 2 Hippocrates, *Decorum* 297 (W. H.S. Jones, trans., 1967). Cited in Thomas WJ: Informed consent, the placebo effect, and the revenge of Thomas Percival. *J. Legal Med.* 2001; 22:313–337.
60. Council on Ethical. Judicial Affairs. American Medical Association. 2010–2011 Ed.. American Medical Association; Chicago: 2010. Opinion 8.12, Patient information. Code of Medical Ethics of the American Medical Association; p. 280-283.
61. Freeman VG, Rathore SS, Weinfurt KP, Schulman KA, Sulmasy DP. Lying for patients: physician deception of third party payors. *Arch. Intern. Med.* 1999; 159:2263–2270. [PubMed: 10547165]
62. Sade RM. Deceiving insurance companies: new expression of an ancient tradition. *Ann. Thorac. Surg.* 2001; 72:1449–1453. [PubMed: 11722024]
63. Dresler C, Cherry M, Sade RM. Should smoking tobacco products in public places be legally banned? *Ann. Thorac. Surg.* 2008; 86:699–707. [PubMed: 18721550]
64. Lehman LS, Kassoff WS, Koch P, Federman DD. A survey of medical ethics education at U.S. and Canadian medical schools. *Acad. Med.* 2004; 79:682–9. [PubMed: 15234922]
65. Helft PR, Eckles RE, Torbeck L. Ethics education in surgical residency: a review of the literature. *J. Surg. Educ.* 2009; 66:35–42. [PubMed: 19215896]
66. Swainson, B. *The Encarta Book of Quotations*. St Martin's Press; New York: 2000. p. 305
67. Cerfolio RJ, Jacobs JP, Sade RM. The ethics of transparency: publication of cardiothoracic surgical outcomes in the lay press. *Ann. Thorac. Surg.* 2009:679–686. [PubMed: 19231369] **This review of how outcomes are measured and how they could and should be measured is one of the best available and most accessible descriptions of outcome database development.

Internet References

101. Division of Cardiothoracic Surgery, Section on Bioethics. [Accessed on August 1 (2011)] Ethics sessions at cardiothoracic surgery meetings.
http://academicdepartments.musc.edu/surgery/divisions/cardiothoracic/ethics_forum.
102. Division of Cardiothoracic Surgery, Section on Bioethics. Ethics sessions at cardiothoracic surgery meetings.
http://academicdepartments.musc.edu/surgery/divisions/cardiothoracic/ethics_bib.htm
103. International Committee of Medical Journal Editors. [Accessed August 1, (2011)] Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Apr. 2010 Available at http://www.icmje.org/urm_main.html.
104. [Accessed August 1, (2011)] *Cruzan v. Director, MDH*, 497 U.S. 1990. p. 261 Available at <http://laws.findlaw.com/us/497/261.html>.
105. [Accessed November 7, 2011] Procedural guidelines for ethics complaints against AATS members. Available at http://www.aats.org/Association/Policies/Procedural_Guidelines_for_Ethics_Complaints_Against_AATS_Mem.html.
106. [Accessed August 1, 2011] Procedural guidelines for handling ethics complaints against STS members. Society of Thoracic Surgeons. Available at <http://www.sts.org/about-sts/policies/procedural-guidelines-handling-ethics-complaints-against-sts-members>.
107. [Accessed on July 30th, 2011] The Common Rule. 1991. Available at: <http://www.nij.gov/funding/humansubjects/common-rule.htm>
108. CNN. [Accessed July 29, 2011] Disgraced cloning researcher convicted in South Korea. Oct 26. 2009 Available at: <http://edition.cnn.com/2009/WORLD/asiapcf/10/26/south.korea.scientist.stem.cell/index.html?iref=alIsearch>.
109. Council on Ethical and Judicial Affairs. [Accessed on August 1, (2011)] Financial relationships with industry in continuing medical education version 5.0 - better but not there yet?.

<http://www.policymed.com/2011/05/ama-ceja-2011-financial-relationships-with-industry-in-continuing-medical-education-version-50-bette.html>.

110. Daily Mail Reporter. [Accessed July 31, 2011] Heroin dealer spared jail to go on transplant list after innovative heart surgery saves his life. MailOnline. Available at <http://www.dailymail.co.uk/news/article-2002214/Heroin-dealer-spared-jail-transplant-list-innovative-heart-surgery-saves-life.html?ito=feeds-newsxml>.
111. [Accessed August 1, (2011)] TSDA weekly curricula. Available at: http://www.tsda.org/sections/integrated_curriculum/Comprehensive%20Requisite%20Thoracic%20Surgery%20Curriculum/index.html.
112. Department of Health and Human Services. [Accessed August 1, 2011] Human subjects research protections: enhancing protections for research subjects and reducing burden, delay, and ambiguity for investigators. Jul 20. 2011 Available at http://www.ofr.gov/OFRUpload/OFRData/2011-18792_PI.pdf.

Executive Summary

Informed Consent

- ◆ Not a piece of paper with a signature, but a process of providing information, eliciting a decision, and obtaining authorization to provide a service.
- ◆ Not a single event, but an on-going process that continuously reevaluates the situation.
- ◆ Cardiothoracic surgeons do not make final decisions, patients do under the guidance of their surgeons.
- ◆ Surrogate/proxy decision makers should be treated with the same respect as the patient: they have ultimate decision making power unless they are deemed incapable or untrustworthy.

Professional Self-Regulation

- ◆ Cardiothoracic surgeons individually and collectively are responsible for the safety of patients, including intentional or unintentional threats to patients from other cardiothoracic surgeons (Bristol Infirmary case).
- ◆ Professional societies can provide disciplinary oversight of their members, as both the STS and AATS have done.

Innovation and Research, Conflicts of Interest and Commitment

- ◆ Innovation is not regulated at all, compared with tightly controlled regulation of research, yet has harmed some patients while benefitting many. Some observers assert that oversight is needed.
- ◆ Disclosure of conflicts of interest is the most frequent method of minimizing harm, but there is evidence that mandating disclosure can actually make the problem worse.
- ◆ There is virtually no high-quality evidence that financial relations of cardiothoracic surgeons with drug and device companies harms patients.

Ethics and the Business Aspects of Cardiac Surgery

- ◆ Cardiac surgeons are increasingly torn between practicing the high quality patient care they were trained to do and the need to maintain revenue to support their offices and families.
- ◆ Increasing scrutiny of cardiac surgical outcomes and publication in the popular press are leading some cardiac surgeons to label high-risk but operable patients as inoperable or referring such patients out of state in order to maintain low mortality rates; risk stratification would help, but there are few reliable tools to accomplish this.

Ethical Controversies in Cardiac Surgery

- ◆ Emotional responses to the social worth of prisoners produces pressures not to provide expensive organ transplants to them, but surgeons should not yield to forces moving them to consider non-medical factors when they make clinical decisions.
- ◆ Clinical equipoise has been central to human investigation design, but it is being challenged as illogical and unnecessary.

- ◆ The dead donor rule has governed eligibility of patients as organ donors, but it might be based on flawed understandings of what constitutes death and how it should be determined; abandoning the DDR could do away with flawed thinking and false justifications, be more honest, and honor the wishes to donate of many who cannot be donors only because they fall short of the DDR.
- ◆ While honesty with patients plays a much bigger role in clinical care than it did for millennia, deception and lying are still alive and well for many cardiothoracic surgeons as they deal with health insurance companies. They should be sensitive to long-term harms from such deceit.
- ◆ Rules and laws that limit resident work hours are based on conflicting data about the effects of sleep deprivation on patient outcomes in surgery and other specialties. Some academic non-surgeons are poised to place similar limitations on practicing surgeons.
- ◆ Health care agents (surrogates and proxies) stand in place of the patient with respect to decision making power, so cardiothoracic surgeons must give them the same deference as they give the patient. A difficult problem is posed by an agent who seems not to be choosing options that the patient would want or that would be in the patient's best interest.
- ◆ Anti-smoking laws seem reasonable in protecting non-smokers from secondhand smoke, but they might be placing unreasonable limitations on smokers while ignoring even greater risks from other sources of potential harm.