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Selected Readings in General Surgery (SRGS) is a topic oriented, in-depth review of the field of general surgery presented eight times annually as an educational offering of the Division of Education of the American College of Surgeons. The mission of the Division of Education is to improve the quality of surgical care through lifelong learning, based on educational programs and products designed to enhance the competence or performance of practicing surgeons, surgery residents, and members of the surgical team. The intent of the publication is to analyze relevant medical literature to give the surgeon the knowledge necessary to practice state-of-the-art surgery. To accomplish this goal, the editor selects 100–125 pertinent articles from the literature for each issue. Each article is reviewed and an overview is written that places the content of these articles in the perspective of the best, day-to-day, clinical practice. In addition to the overview, 12–18 full-text articles are reprinted in each issue.

The overview is compiled with the assistance of an 18-member, international board of editors who are experts in the various focus areas that comprise the specialty of surgery. In addition, the editorial board has representation and expertise in such important fields as medical evidence evaluation, surgical education, outcomes research, standard setting, and performance improvement. *SRGS* is a unique resource because the overview and selected full-text articles provide the reader with the most valuable and pertinent content illuminated with informed opinion and critique. Unnecessary material is eliminated. *SRGS* does not present itself as infallible and the editor-in-chief takes responsibility for the content that appears in each issue. The editor-in-chief and the editorial board recognize that there is no such thing as the "average" surgical patient, and that the information in the literature must be interpreted in the light of the clinical presentation of each individual patient.

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Literature Overview

Editor in Chief: Lewis Flint, MD, FACS
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Steven Steinberg, MD, FACS, and Larry Kaiser, MD, FACS

CME Pretest | ETHICS, PATIENT SAFETY & THE BUSINESS OF MEDICINE

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To earn CME credit, completing the pretest is a mandatory requirement. The pretest should be completed BEFORE reading the overview and taking the posttest. Both tests must be completed online at *www.facs.org/publications/srgs/cme.*

1. The informed consent process serves to protect which of the following ethical concepts?

a) Autonomy
b) Utilitarianism
c) Justice
d) Moral Fiduciary
e) Nonmaleficence

2. In surgical ethics, what does the term "moral fiduciary" means?

a) The surgeon should behave in a way that satisfies the economic needs of the surgeon
b) The surgeon should seek to accomplish the economic goals of the hospital
c) The surgeon should put the needs of the patient first
d) The surgeon should follow the wishes of the patient's family
e) If the patient wishes to dictate the choice of a medical device, the surgeon should consent to this without discussion

3. A 92-year-old man who is chronically wheelchair bound due to a prior stroke is admitted to the emergency department hypotensive due to a free intraperitoneal rupture of an abdominal aortic aneurysm. Rapid assessment of the patient convinces the surgeon and the anesthesiologist that chances of survival and recovery are slim. In discussing with family members the advisability of operation in this patient, which of the following terms should not be used?

a) Quality of life
b) Long-term ventilator support
c) Dialysis
d) Futility
e) Patient preferences

4. A 79-year-old woman with multiple bone and brain metastases from breast cancer is admitted to the intensive care unit comatose and with clinical evidence of severe pneumonia. She is intubated and put on a ventilator. The metastases are resistant to chemotherapy. An advance directive states the patient does not wish to have futile therapeutic interventions. The family wants the advance directive be enforced. All of the following statements are true regarding this clinical problem except which one?

a) A feeding tube will make the patient more comfortable
b) The family should be allowed unlimited access to the patient
c) Heart rate and blood pressure monitors should be turned off
d) The family should be assured that treatment for dyspnea and noisy breathing due to secretions will be employed promptly when needed
e) Healthcare team members should visit the patient and family frequently

5. Which of the following practices is permitted under current rules governing ethical surgical research?

a) Data can be published if obtained using a study protocol approved by the appropriate institutional review board
b) Data can be published if obtained against patient wishes
c) Data obtained in a foreign country can be published if the foreign government states that patient consent is not necessary
d) Data obtained from prisoners without permission can be published
e) Data obtained from autopsies of prisoners without permission can be published

6. Each of the following is an important component of caring behavior in surgeon-patient communication except which one?

a) Allocating sufficient time for the meeting
b) Allowing the patient and/or family time to express their feelings and opinions
c) Making certain that terms are understood
d) Providing a written summary of the meeting
e) Providing hopeful but realistic assessments

7. Which of the following is true regarding medical error reporting?

a) Only errors resulting in patient death need to be reported
b) Patients are more likely to sue for malpractice if an error is reported
c) There is a federal law requiring reporting of medical errors to patients
d) Reporting of errors to a central state agency is required of all acute care facilities, physician practices, and nursing homes
e) Disclosing and apologizing for a medical error reduces the chance of litigation

8. Which of the following is true regarding checklist-directed preoperative briefings?

a) The briefings do not reduce risk-adjusted mortality
b) Briefings are effective only in hospitals with plentiful resources
c) Risk adjusted morbidity rises after introduction of the briefings
d) Mortality and morbidity are reduced after introduction of briefings
e) Briefings require an unacceptable amount of time

9. Effective organizational change occurs when leaders are able to accomplish all of the following except which one?

a) Anchor a new behavior in the organization
b) Create a credible vision
c) Obtain funding for the project
d) Create a sense of urgency
e) Produce positive short-term results

10. The original intent of the surgical "time-out" mandated by national hospital accrediting agencies was?

a) Reduce the risk of postoperative infection
b) Eliminate the risk of wrong patient, wrong site surgery
c) Reduce the risk of perioperative cardiac events
d) Reduce the cost of total joint replacement
e) Increase the use of sequential compression stockings

11. Surveys assessing the level of teamwork in the operating room have disclosed all of the following except which one?

a) Nurses' ratings of surgeon levels of teamwork are higher than surgeons' ratings
b) Surgeons' ratings of teamwork levels of other surgeons are consistently high
c) Surgeons' ratings of teamwork of nurses are low
d) Surgeons' ratings of teamwork of anesthesiologists are low
e) Residents' ratings of attending surgeons are consistently low

12. Which of the following is true regarding delays in the operating room?

a) Preoperative briefings contributed to delays
b) Delays were decreased when preoperative briefings were implemented
c) Preoperative briefings require, on average, 10 minutes
d) Anesthesia residents participating in briefings contributed to increased delays
e) Nursing participation in briefings increased the average duration of the briefings

13. A business intervention to improve a medical process is "scalable" when?

a) The intervention is cost-effective
b) The intervention is rapidly accepted by medical staff members
c) The intervention increases hospital revenue
d) The intervention increases patient satisfaction
e) The intervention can be successfully used in multiple hospital settings

14. Each of the following has been shown to improve operating room efficiency except which one?

a) Scheduling of operations with highly predictable durations early in the day
b) Improving hospital discharge efficiency
c) Formal education of surgeons to decrease tardiness
d) Improving environmental services to reduce intervals between procedures
e) Implementing meetings to facilitate free exchange of views between surgeons and hospital administration

15. The desired outcome of an Accountable Care Organization (ACO) is which of the following?

a) Improved profit margin
b) Delivery of complex health services
c) Improved population health
d) Health system consolidation
e) Increased recruitment of medical specialists

16. Reductions in health system waste could result in annual savings of which of the following amounts?

a) $2 billion
b) $360 million
c) $4.5 billion
d) $765 billion
e) $28 million

17. Potential approaches to healthcare cost savings could include all of the following except which one?

a) Reduced number of emergency treatment facilities
b) Reduced administrative costs
c) Improved use of nonphysician providers
d) Required price transparency for all services
e) Reduce costs of defensive medicine

18. The main reason patients use retail clinics is which of the following?

a) Lower out-of-pocket costs
b) Availability of surgical consult services
c) Higher quality of care
d) Convenience
e) Availability of radiologic services

19. The most common location for retail clinics is which of the following?

a) Rural communities
b) Low-income areas
c) African-American neighborhoods
d) Affluent communities
e) Latino neighborhoods

20. The most common result observed after health care mergers is which of the following?

a) Improved health outcomes
b) Increased data sharing
c) Increased cost
d) Decreased wait times for medical services
e) Increased emphasis on quality

Introduction | ETHICS, PATIENT SAFETY & THE BUSINESS OF MEDICINE

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This issue of *Selected Readings in General Surgery* (*SRGS*) will review recent literature on three topics that are important to surgeons but are not covered in depth in the typical organ system-focused *SRGS* issues—surgical ethics, patient safety, and the business of health care. I am grateful for the editorial assistance of several thought leaders in these fields: perspectives and articles dealing with surgical ethics were provided by Mark Weissler, MD, FACS. Patient safety issues were reviewed and articles selected by Steven Steinberg, MD, FACS. Articles on the business of health care were provided by Larry Kaiser, MD, FACS. We hope you will find value in this information and, hopefully, some useful items that may enhance and improve your surgical practice.

Surgical Ethics

During the past decade, there has been an increasing emphasis on the need for surgeons to be familiar with the fundamentals of an ethical surgical practice. Several societal factors have served to accentuate this trend, including a new recognition of the importance of personal freedom and autonomy; patients are now more actively involved with the decision to seek, consent to, and even refuse surgical care. Tied to this are two other important factors: confusion and conflict. Conflicting information and expectations, too often unanticipated, sometimes place the surgeon in an adversarial relationship with patients and their families. Many times, this uncomfortable state occurs because of the inability of the surgeon, the patient, or the family to comprehend the uncertainty associated with predicting the outcomes of diseases and treatments—technological advancements in surgery, particularly in surgical critical care, have complicated the surgeon's ability to provide accurate prognoses. Additional factors leading to confusion and conflict include the variability of opinions expressed by different specialists participating in the care of a patient's illness and misunderstandings that arise because of the direct marketing of medications and other treatments directly to patients.

Recognition of the need for the education of both surgeons and their patients in ethics led to the development of a statement of principles of ethical practice by the American College of Surgeons (ACS). This statement is reproduced as Figure 1. Furthermore, the ACS has a committee on ethics that is preparing a surgical ethics textbook. Readers are urged to watch for this publication, which is anticipated to be released in 2016.

As an example of educational efforts in surgical ethics, several articles have emerged from a series of ethics conferences developed by Ira Kodner, MD, FACS; these articles have appeared in the journal *Surgery* and will be referenced frequently in the following discussion.

Dr. Kodner[1] delivered the annual Ethics and Philosophy Lecture during the ACS' 2008 Clinical Congress. This lecture was published in the *Journal of the American College of Surgeons,* 2009. In his presentation, Dr. Kodner made a strong case for surgeon participation in ethical discussions within hospitals, in the ethics education of students and residents, and on committees that provide ethics consultations to clinicians. For example, in a description of a survey conducted in his home institution, he acknowledged the small amount of interaction and discussion of ethics' challenges between attending surgeons and residents. The survey exposed the fact that residents had discussed with faculty ethical problems presented during the care of their patients in only 25% of instances. This finding led to the initiation of a regular conference devoted to challenges in surgical ethics, and

Figure 1 American College of Surgeons Code of Professional Conduct. Reproduced with permission from the American College of Surgeons.

As Fellows of the American College of Surgeons, we treasure the trust that our patients have placed in us, because trust is integral to the practice of surgery. During the continuum of pre-, intra-, and postoperative care, we accept responsibilities to:

- Serve as effective advocates of our patients' needs.
- Disclose therapeutic options, including their risks and benefits.
- Disclose and resolve any conflict of interest that might influence decisions regarding care.
- Be sensitive and respectful of patients, understanding their vulnerability during the perioperative period.
- Fully disclose adverse events and medical errors.
- Acknowledge patients' psychological, social, cultural, and spiritual needs.
- Encompass within our surgical care the special needs of terminally ill patients.
- Acknowledge and support the needs of patients' families.
- Respect the knowledge, dignity, and perspective of other health care professionals.

Our profession is also accountable to our communities and to society. In return for their trust, as Fellows of the American College of Surgeons, we accept responsibilities to:

- Provide the highest quality surgical care.
- Abide by the values of honesty, confidentiality, and altruism.
- Participate in lifelong learning.
- Maintain competence throughout our surgical careers.
- Participate in self-regulation by setting, maintaining, and enforcing practice standards.
- Improve care by evaluating its processes and outcomes.
- Inform the public about subjects within our expertise.
- Advocate strategies to improve individual and public health by communicating with government, health care organizations, and industry.
- Work with society to establish just, effective, and efficient distribution of health care resources.
- Provide necessary surgical care without regard to gender, race, disability, religion, social status, or ability to pay.
- Participate in educational programs addressing professionalism.

As surgeons, we acknowledge that we relate to our patients when they are most vulnerable. Their trust and the privileges we enjoy depend on our individual and collective participation in efforts that promote the good of both our patients and society. As Fellows of the American College of Surgeons, we commit ourselves and the College to the ideals of professionalism.

Kodner stressed that the free and open discussions held in these conferences emphasize the importance of ethics in surgical practice.

In his lecture, Kodner also noted the influence of time on surgical ethics: surgeons are called on to make rapid life-and-death decisions, often without sufficient time to obtain in-depth information from the patient and their family. Surgeons are asked to deliver bad news, make decisions about the indications for a surgical procedure, obtain informed consent, and assist patients at the end of life as decisions are made related to interventions to maximize the quality of remaining life—all of these tasks are undertaken in an atmosphere where economic concerns have reduced the amount of time a surgeon can spend with a patient. Also, problems in teaching and discussing ethical issues have been created by duty hour regulations, which reduce the amount of personal mentoring between surgical educators and learners.

Kodner cited data indicating that the vast majority of ethical challenges for surgeons relate to achieving a positive balance between the medical indications for a treatment and patient preferences regarding treatment. A smaller proportion of ethics challenges relates to quality of life and various contextual features of the surgeon-patient relationship; these contextual features include various issues that may affect treatment strategies, including family preferences, surgeon attitudes, economic factors, religious beliefs, research, and surgical training. Determining the quality of life preferred by the patient is often difficult because patients and their families have varying opinions of "satisfactory quality of life" and some opinions often conflict with the surgeon's assessment of the patient's current and expected quality of life. Examples of ethical challenges related to contextual issues include the need to advise patients who require an emergency operation to prevent death within a short interval—often there is a significant intraoperative death risk and a small chance of short-term and long-term survival. The surgeon faces the task of determining whether the patient would prefer to risk dying intraoperatively or to spend their remaining few hours of life with loved ones.

In an earlier publication,[2] Kodner emphasized the importance of the surgeon-patient relationship, and explained that this relationship is based on a bilateral commitment to "truth telling." The importance of thorough informed consent was stressed. As previously stated, economic and time pressures of practice often help influence ethical challenges; it is imperative that surgeons take time to develop a relationship with their patients, despite reductions in the amount of time available for this purpose. In modern surgical practice, the surgeon-patient relationship is, of necessity, a shared responsibility involving all members of the care team, including practice partners, residents, physician assistants, and nurses. Multiple influences have driven this change in practice, including the move to prescribed duty hours during training, increasing complexity of surgical care, reduced time available to spend with patients, and the need to integrate institutional and surgeon-specific care processes. Therefore, the need to develop a positive and reliable team function is critical to the success of this approach to the surgeon-patient relationship. This specific topic will be reviewed in detail in a later section of this overview.

Important Terms in Surgical Ethics

The foundation of our current understanding of ethics was laid in the writings of Socrates and Plato. The fundamental principles within these texts have undergone repeated revisions by generations of scholars. Redefinition of these basic principles has been necessitated by the continued evolution of societies and human beings. The works that have accumulated over the eras of human history reflect the struggle to define and practice the "right thing to do." The scholarship of medical ethics has also become complex. For the sake of clarification, we will devote a brief amount of time to introduce and define several accepted terms used in surgical ethics discussions; these will be modified, as necessary, to make them pertinent to our discussion of the ethics of surgical practice:

Utilitarianism: In its most straightforward definition, utilitarianism is the term applied to actions that produce the greatest "good" for the greatest number of members of a society. Classically, the writings of John Stewart Mill and Jeremy Bentham have stressed the classic definition of utilitarianism that emphasizes the use of actions that lead to the largest amount of "happiness"

for the largest proportion of a society. Many philosophic arguments debate whether "happiness" can be equated with "good." For purposes of surgical ethics, utilitarian principles form the foundation for our understandings of terms such as "autonomy," "justice," and "beneficence," defined subsequently.

Justice: Fundamentally, the concept of justice refers to the provision of necessary goods and services to members of a society in a fair and equitable manner. Classically, this definition referred to the provision of protections from government to citizens of a society so that members of the society could pursue the "fundamental rights of humans" (life, liberty, and the pursuit of happiness). Debate has arisen relative to the necessary "qualifications" of a member of society to receive the benefits of societal membership. The understandings of the "qualifications" necessary to receive the benefits of societal membership have led to the development of concepts of "distributive justice." Obviously, perversions of the definition of justice can occur if "qualifications" for receiving goods and services are determined on the basis of characteristics such as skin color that have no bearing on societal contributions. Other perversions occur if qualifications are determined based on religion or group membership. Discussions of distributive justice center on the distribution of goods and services as an equal share to all members, distribution based on need, allocation based on merit or societal contributions, or allocation based on the provision of a functioning free market. The notion that some members of society are disadvantaged, through no fault of their own, because of factors within the society that produce the disadvantaged state, leads to the ongoing political debate over the role of government in the correction of societal dysfunctions. A recent example of this debate is the painful array of arguments heard along the road to passage of the 2010 health reform bill and the contentious words disputing the need for and "rightness" of legislation that would provide health care coverage for all Americans.

For surgeons, problems related to distributive justice arise most frequently when available treatments are in short supply. One immediate example of a problem of distributive justice is the allocation of donor organs to transplant patients. Development of plans to allocate scarce resources leads to the emergence of arguments over how to provide the "greatest good for the greatest number." During mass casualty situations, surgeons are required to make decisions about the allocation of surgical care to injured patients in a setting where health care resources may be overwhelmed. Advanced planning for such events is obviously crucial to success. Fortunately, ethics-based societal discussions have led to workable solutions to most of the surgical problems related to distributive justice.

Moral Fiduciary: When assuming the care of a patient, the surgeon assumes the role of "moral fiduciary." This term refers to the fundamental assumption that the surgeon will put the needs of the patient first. Basing surgical care decisions on the self-interest of the surgeon is, obviously, a departure from acceptable ethical behavior. Using a treatment, implant, or drug because of the financial interests of the surgeon is an example of this kind of unethical behavior.

Autonomy: The fundamental right of self-determination is the basis of autonomy. In surgical ethics, autonomy most often becomes important in patient care decisions where patients decide against a needed therapy or when patients request a treatment that is deemed by the surgeon to be inappropriate or potentially harmful. One of the most perplexing problems of patient autonomy currently facing surgeons relates to interpretation of patient wishes when the patient cannot communicate those wishes. Family or other persons authorized by a durable power of attorney may need to assume the responsibility for determining and carrying out patient wishes. In many instances, these individuals are burdened with erroneous information (what the patient might have said) or conflicted feelings ("What I would do were I in the position of the patient"). Unfortunately, "advance directives" or "living wills" are often not available or, frequently, do not address the specific problem faced by the patient, family, and surgeon.

Beneficence: This is the term applied to the practice of providing the best, safest, and most compassionate care to every patient for whom the surgeon is responsible. Success in practicing beneficent surgery depends on a working knowledge of the evidence in support of the therapies available, knowledge of the unique aspects of the illness as it presents in the patient at hand, a thorough understanding of the patient's wishes, and the technical skill to execute the needed operation.

Nonmaleficence: This refers to the conduct of practice in keeping with the admonition to "first, do no harm." "Harm" requires redefinition for each individual patient. Patient wishes, the cultural background of the patient, and realistic estimates of the potential for achieving the quality of life desired by the patient will need to be continually reassessed. In daily clinical practice, performance in keeping with this ethical concept may require withholding an operation that is potentially curative because the patient cannot survive the procedure due to severe comorbidities, or because the operation (or the advanced stage of the underlying disease) would result in a disability, thus failing to help the patient achieve their desired quality of life.

Futility: The concept of futility is inexorably related to the concept of nonmaleficence. Futile procedures are those that will not alter the course of the underlying disease. Surgical futility is also encountered when the proposed treatment will not benefit the patient (in terms of quality of life), even though the operation may slow or stop the disease process.

The History of Surgical Ethics

A review article that provided an overview of the history of surgical ethics was by Namm and coauthors[3] in the *World Journal of Surgery,* 2014. The authors emphasized that the eighteenth century was a time of major developments in surgery, with the recognition of surgeons as clinical experts with the establishment of the Company of Surgeons in 1745. Surgeons visibly separated themselves from other medical caregivers. Surgical practice was significantly different from the practices of nonsurgeons. The doctor-patient relationship between physicians and their patients tended to occur in private, whereas surgical procedures were frequently performed before audiences consisting of other surgeons and surgeons in training. Also noteworthy was the fact that the governing principle of medical practice, embodied in the term "do no harm," was not incorporated into surgical practice at this time, since surgeons had to "harm" patients with the scalpel and the surgical procedure in order to improve or cure their diseases. A final important difference between surgery and nonsurgical specialties was the fact that the surgeon had a relatively short time interval to establish a relationship of trust with the patient.

The first important figure in the development of surgical ethics discussed in the article by Namm and coauthors was John Gregory, a physician and moralist from Scotland. Gregory believed that surgeons were equal in the hierarchy of medical professionals with all other practitioners and that high ethical standards should govern the behaviors of health care professionals. For example, he noticed that medical practice was conducted mostly with the self-interest of the practitioner as the prime factor. Gregory urged that medical professionals develop "sympathy" that would permit them to feel for the suffering of the sick and to have a strong desire to relieve this suffering. Gregory also urged surgeons to assist patients in understanding their diseases and the procedures that would be used to treat them. These insights helped to establish the patient as the focal point of the surgeon-patient relationship.

The second key figure discussed in the article was Thomas Percival. Percival advanced the idea of consultation prior to a surgical procedure and described a medical team approach to patients, with physicians and surgeons working together for the good of the patient.

Two advances in the mid-nineteenth century transformed surgery from a profession that required speed and technical skill to a professional activity that could be used to treat conditions within the major body cavities of patients. These two developments, anesthesia and asepsis, permitted the delivery of surgery without pain and the development of the sterile operating room. Namm and coauthors noted that abdominal operations were considered unethical prior to the development of anesthesia and asepsis; however, by 1886, the Massachusetts General Hospital had established an abdominal surgery ward, and in the years 1899 and 1900, more than 800 abdominal surgical procedures were performed at the Pennsylvania hospital in Philadelphia.

The next major development in the evolution of a system of surgical ethics was the prevention of practices such as fee-splitting and itinerant surgery. A key figure in this era of ethical development was Franklin Martin, who envisioned a surgical society that would standardize surgical practice for the benefit of surgeons and for the protection of the rights of patients. Martin led the initiative that resulted in the formation of the American

College of Surgeons, and this organization began the effort to eliminate fee-splitting by denying fellowship in the College to surgeons who participated in this practice. Of interest is the fact that other professional organizations, such as the American Medical Association (AMA), did not support this effort.

Martin also initiated the push to suppress itinerant surgery, based on the principle that no relationship was established between the patient and the surgeon in many instances of this practice. Martin believed and convinced others to believe that itinerant surgery violated a central ethical principle in the practice of surgery. As this effort matured, surgeons began to see themselves as professionals who were obligated to uphold a professional and fiduciary relationship with patients that dictated that the surgeon determines the need for operation and conducts the preoperative, intraoperative, and postoperative care.

Progress in surgery such as organ transplantation and minimally invasive surgery have raised unique issues in ethics. These topics will be reviewed in subsequent sections of the overview.

Surgical Ethics: General Considerations

The fundamental principles of surgical ethics and approaches to providing training in surgical ethics, as well as methods for solving ethical problems encountered in surgical services, will be discussed in this section of the overview. Several articles will provide perspective on two potentially difficult ethical challenges: truth telling and the management of futility and other difficult end-of-life topics.

Many of the articles reviewed in this section and many of the perspectives provided in other sections of the overview were drawn from two symposia that focused on surgical ethics and that were published in the *World Journal of Surgery* in 2014. Several important aspects of surgical ethics were explained in the introductions of these symposia.[4,5] The authors of these introductions pointed out that there are features of surgical ethics that are unique. The procedural nature of surgery and the fact that bodily and psychic damage are imposed in order to treat the underlying disease force modifications of the ethical concepts of rights, justice, and equality. The moral domain of the surgeon-patient relationship has features that are different from those encountered in the field of general medical ethics; these features include rescue, proximity, ordeal, aftermath, and presence.

The authors of the symposia introductions stated that the characteristics of a modern competent surgeon include excellent clinical and technical skills and a willingness to acquire knowledge of and pursue the practice of humanism, ethics, and moral values. The effective practice of ethical surgery implies dignity, tolerance, and respect. The welfare and rights of the patient assume the uppermost position in the surgeon-patient relationship. Current understandings of the ethical practice of surgery recognize the right of all patients to be adequately informed about their care, the right to be treated by a competent surgeon, the right to have their values placed above those of the surgeon, the right to decide whether or not to accept an operation, the right not to be harmed by negligence, and the right not to be deceived.

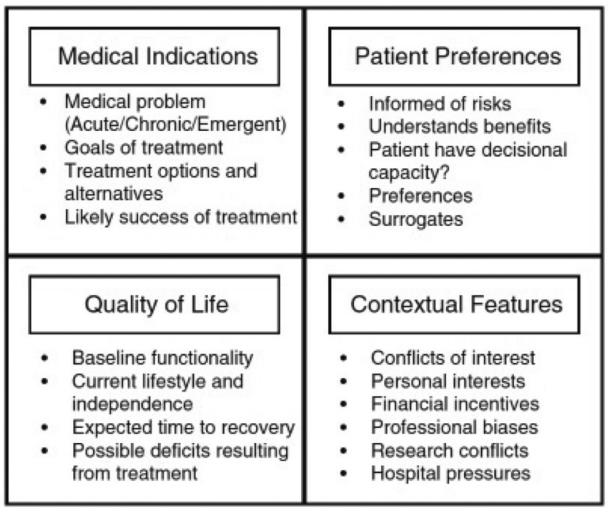
An article that described an approach to managing complex ethical problems that arise in surgical services was by Wightman and Angelos[6] in the *World Journal of Surgery,* 2014. This article is included as a full-text reprint accompanying some formats of *SRGS*. The authors described a clinical scenario where a patient who was living independently at the time of a colon cancer diagnosis and who chose not to have surgery presented with an acute abdomen thought to be caused by colon perforation. At the time of the emergency situation, the patient requested that surgery be performed. To help solve complex problems in surgical ethics like this, Wightman and Angelos recommended using the "four box" model described in a book by Jonsen and coauthors.[7] This model is illustrated as Figure 2.

The first box considers the medical indications for treatment of the disease. In the acute situation described above, there are three alternatives: (1) do everything possible to support organ function and correct the condition causing the acute abdomen with a surgical procedure, if possible; (2) continue current treatments, but do not escalate; and (3) withdraw all treatment.

The medical condition, the treatment alternatives, and the attendant risks and benefits need to be explained to the patient and family. An informed consent conversation forms a bridge to the second box, where patient preferences are determined. The ability of the patient to make

Figure 2

The four-box approach to managing ethical problems in clinical practice. Based on and adapted from Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine, Sixth Edition, Jonsen and coauthors.[7] Copyright McGraw-Hill Education (2006). Reproduced with permission.



decisions is an important assessment at this stage. The preferences of the patient and surrogate decision makers are quantified at this stage as well.

In the third box, quality of life at baseline and predicted quality of life assuming successful treatment are assessed and the potential long-term outcomes are described to the patient and/or surrogates. In this situation, if the patient survives and the resection of the colon cancer is complete, quality of life equivalent to the baseline quality is possible. In the fourth box, the personal interests, financial interests, and biases of all of the people involved in the case are assessed. In some situations, a patient's prior wishes may be different from the wishes of a surrogate decision maker. In this setting, the surgeon must determine reasons for the differences and attempt to rationalize the differences.

The authors concluded by recommending that the above steps be adopted and that data on the successes and limitations of their application in actual patient care settings be gathered and analyzed to determine the need for modifications.

It is intuitive to conclude that effective management of ethical problems in surgical practice will more likely occur if there is a formal education effort to prepare surgeons for these situations. Keune and Kodner[8] examined this topic by in the *World Journal of Surgery,* 2014. Creation of an ethics curriculum can lead to important and enlightening discussions of what it means to be a "good surgeon." In addition, it can introduce concepts and methods for approaching ethical problems that can be incorporated into actual practice situations. The curriculum can assist surgeons in managing the problem of "underdetermination." This problem frequently arises when caregivers realize that there is not sufficient scientific evidence to make a precise determination of the best course of action to care for a patient. A formal ethics curriculum can also prepare surgeons to be leaders in their institutions as formal protocols for managing ethical challenges are developed and implemented. Finally, the ethics curriculum can assist surgeons in managing the conflicts and challenges to moral values that surround the introduction of new techniques and new technologies into clinical practice. The authors recommended that all surgical residency programs develop an ethics curriculum.

An important, but sometimes challenging, ingredient of ethical surgical practice involves "telling the truth"; what is the appropriate course of action when disclosing all of the truth in a situation where prognosis is poor will harm the patient because learning the complete truth will destroy hope? Questions arise as to the nature of truth, the identification of information that can be withheld without violating ethical principles, and the best methods of disclosing information to the patient.

Suri and coauthors[9] reviewed these issues in the *World Journal of Surgery,* 2014. This article is supplied as a full-text reprint accompanying some formats of *SRGS*. The authors opened their review by noting that the nature of truth may change with time and with the development of new knowledge. They cited data supporting the conclusion that the life expectancy of "truth" in scientific literature is finite; data showed that the half-life of a scientific truth was 45 years. In addition, the truth concerning a patient's clinical condition and prognosis may also change with time. For these reasons, knowing the "truth" at a specific time in the process of caring for a patient is essential to knowing what information should be provided to the patient. Furthermore, the process of providing information may contain errors both in the way that information is delivered to the patient by the surgeon and in the way the patient understands the information. Data cited by the authors confirmed that surgeons frequently discuss

prognosis in terms of risk of mortality, but often do not inform patients of the possibility that long intervals of intensive care and ventilatory support may be required for recovery to occur. Patients, on the other hand, frequently do not understand the terminology used and do not retain all of the information provided. Often facts provided to the patient do not aid in the development of "wisdom" on the part of the patient to understand the prospects for recovery and resumption of a normal quality of life. The authors cited additional data that show the importance of an effective surgeon-patient relationship in the process of disclosing the truth in a clinical situation. A relationship of mutual trust and respect can make even the disclosure of the worst news acceptable to the patient and lead to a level of understanding that benefits the patient and the family. Such relationships require the use of sensitive, sincere, and hopeful language and expenditure of effort to understand the values, moral structure, and preferences of the patient and the family.

Another perspective on the disclosure of "truth" to the patient was presented in an article by Sarafis and coauthors[10] in the *Global Journal of Health Science,* 2014. The authors conducted a review of available global literature to determine the extent to which truth is disclosed to patients and to examine factors that influence the delivery of truthful information. The authors pointed out that the stress felt by health care professionals when they attempt to honestly inform patients occurs because most of these encounters require the presentation of bad news. In these encounters, it is important to know when forcing the truth on patients will be harmful, thus making it necessary to alter the manner and time course of delivery of information. Data cited by the authors show that while most patients want as much information as possible, a substantial minority would rather have especially negative information withheld or delivered gradually. It is important, therefore, for the surgeon to attempt to determine which group the patient resides in. In some instances, family members will request that bad news be withheld from the patient. Data cited in the article supports the conclusion that this often results in worse outcomes in terms of damage to the surgeon-patient relationship. The authors noted that barriers to effective delivery of truthful information include lack of time, lack of an appropriate place to have the conversation, and language problems. Most of the data examined in the review described in the article support the fact that withholding the truth damages the surgeon-patient relationship. For this reason, the question becomes not one of withholding the truth from the patient, but of finding an effective and merciful way to deliver the information.

The final article reviewed in this section is a clear and insightful discussion of the elements of medical professionalism as it is understood in modern medical practice; the article was by Pellegrino[11] in the *Mount Sinai Journal of Medicine,* 2002, and is supplied as a full-text reprint accompanying some formats of *SRGS*. The author offered valuable advice on incorporating professionalism into medical practice to help improve efficacy and fairness for both patients and professionals who participate in modern systems of care. The article contains valuable "pearls" that could be lost as the article is summarized; for this reason, I strongly urge readers to review this content in its entirety.

The Ethics of Informed Consent

In their article in the *World Journal of Surgery,* 2014, Cainzos and González-Vinagre[12] noted that informed consent for surgical procedures became a matter of law in 1914, when the Cardozo decision was handed down in the case of Mary Schloendorff. Several other legal decisions followed, and now there are laws in every state and in most countries that require that informed consent be documented prior to initiating surgical procedures. The authors also pointed out that there have been major evolutionary changes in the relationship between the patient and the surgeon. This relationship has moved from a paternalistic structure to one based more on patient-centered decisions; documentation of consent that includes reference to patient attitudes and preferences is now commonplace. The structure of the conversation leading to informed consent has, of necessity, changed to include assessments of patient preferences and questions that are designed to confirm patient understanding of the potential risks and benefits of the operation to the fullest extent possible. The most commonly employed model of information presentation, according to the authors, is the "balanced" model, wherein the patient is presented with information relevant to risks, benefits, and alternative treatments.

In a subsequent section of the article, the authors described the components of informed consent. These include a section of preconditions, wherein the competence of the patient is described and confirmation of the "voluntariness" of the consent is noted. In the absence of the necessary level of competence, the consent decision is ceded to a legally appointed surrogate. The next component includes the information provided to the patient. Providing the correct amount of detail to the patient may be challenging because of time pressures. Ideally, information relevant to the risks and benefits of the proposed procedures could be delivered over the course of more than one conversation as information from ancillary laboratory and imaging studies becomes available; obviously, delivering the ideal amount of information in the setting of an acute illness that damands urgent treatment may be impossible.

Givel and Meier[13]provided perspective on the amount of information needed by patients in order to make an informed decision regarding a proposed surgical procedure in the *World Journal of Surgery,* 2014. The authors cited data indicating that patients may not wish to have exhaustive information, and that if the patient is required to read and understand a very detailed consent form, the form may not be read and understood in its entirety. Data also confirmed that the situation in which patients and families want the most detailed information occurs when a child is scheduled to undergo an operative procedure.

Givel and Meier pointed out that data is sparse concerning the effects of anxiety on the informed consent process; one comprehensive review of the literature cited in the article could not confirm a significant relationship between anxiety levels and completing the consent process.

The authors recommended introducing patients and their families to resources such as the informed consent information list available on the ACS website at *www.facs.org*. They also recommended that patients be made aware of the possibility of acquiring a second opinion, if feasible given the clinical circumstances.

An article that reviewed data relevant to the extent of patients' understanding of information provided about their surgical care was by Pugliese and coauthors[14] in the *World Journal of Surgery,* 2014. The authors emphasized that, ideally, patients should understand their medical problem, the proposed treatment, available alternatives, the consequences of accepting or refusing the treatment, and the option to refuse if so desired. Surgeons charged with the responsibility of delivering understandable information to the patient must be aware of the need for patient autonomy, as well as understand that the patient is suffering not only from their disease, but also from the psychological burden imposed by that suffering. The authors recommended that surgeons consider the level of understanding that is possible for each patient. In some instances, it may be helpful to include a multidisciplinary group in the process of obtaining informed consent to make certain that the amount of information desired by the patient has been successfully presented.

Cainzos and González-Vinagre[12] noted that, according to survey data cited in the article, disclosing the surgeon's experience with the proposed procedure is considered important by the majority of patients. Most patients felt that they needed to know if the surgeon was performing the procedure for the first time, and a large proportion of the surveyed patients felt that a description of the extent of the surgeon's experience with the proposed operation was important for decision-making.

Documenting the extent of patient understanding of the information presented is important as well; however, data cited by Cainzos and González-Vinagre confirmed that patient understanding is frequently incomplete. In a cited study, fewer than half of patients could recall information that had been presented about the morbidity risk of a proposed operation and only 20% could recall information regarding mortality risk. It was encouraging, however, that the data cited disclosed that nearly 75% of patients could recall information that was presented concerning postoperative quality of life. The main concerns of patients in this area of knowledge were the potentials to return to work and to normal activity levels.

Additional information relevant to the ethical aspects of disclosure of surgeon experience was presented in an article by Ganai[15] in the *World Journal of Surgery,* 2014. The author noted that there is continuing uncertainty as to whether there is an ethical obligation to disclose surgeon experience. In the article, the author described a personal experience involving an informed consent conversation he had with a patient. The patient asked him about his experience, and Ganai revealed that the

proposed procedure would be the first he had performed as an independent practitioner, although he had participated in a significant number of the procedures during training. He offered the patient the opportunity to obtain a second opinion and described the processes used in the hospital to ensure that the procedures were performed as safely as possible. After a short interval of consideration, the patient consented to the operation and the author felt that both he and the patient had benefitted from conducting the informed consent conversations in this way. The author noted that the process of considering disclosing surgeon experience during the process of informed consent is made easier if there is a careful personal assessment of the balance between the level of risk of a procedure and the experience of the surgeon; seeking the advice of senior surgeons may be helpful in this process. The need to provide information that is honest and helpful to the patient's decision-making process may dictate that an honest statement of experience as it relates to risk of an adverse outcome is a necessary component of the informed consent conversation.

Cainzos and González-Vinagre[12] listed risk factors for incomplete understanding of informed consent content that included older age, African-American ethnicity, lower levels of education, and shorter conversations. Suggestions for minimizing risk of misunderstanding include increasing conversation time, using explanatory written materials, offering multimedia decision aids, using Internet sources, presenting information regarding available clinical practice guidelines, and using repeat conversations when feasible. The authors noted that a list of questions that should be posed by the patient to the surgeon is available on the ACS website at *www.facs.org*.

If the information provided to the patient is clear, understandable, and as complete as possible, a discussion involving both the patient and family members is appropriate prior to a decision-making conversation. After this, a document describing the operation, expected benefits and risks, and possible alternative approaches can then be signed by the patient.

Additional perspective on the challenges of informed consent were presented in an article by Grady[16] in the *New England Journal of Medicine,* 2015. This article is supplied as a full-text reprint accompanying some formats of *SRGS*. The author stressed the point that the informed consent process is not solely a matter of a patient making an autonomous decision; key influencers may include loyalty, compassion and solidarity, as well as cultural influences that may affect moral values. Understanding the effect of culture on the informed consent process is important, and these influences need to be considered in order to help protect the patient's autonomy. Grady stressed the importance of recognizing the challenges of informed consent for patients contemplating treatments and participating in research studies. Continued refinement of the informed consent process will be possible as additional research is done to further understand all of the emotional and physical factors that influence the thinking of patients and health care providers who are called upon to participate in the informed consent process.

An article that described the necessary elements of an informed consent form that would satisfy legal and ethical requirements was by Abaunza and Romero[17] in the *World Journal of Surgery,* 2014. Readers are encouraged to review this article in its entirety.

An example of a challenging problem in the area of informed consent occurs when family members request a surgical procedure on a relative who is mentally impaired. This subject is discussed in an article by Caralis and coauthors[18] in *Surgery,* 2008. The article begins with a description of a patient with Down syndrome who can be employed outside of the home and who has expressed a wish to be a parent. The mother and father of the patient request that the patient undergo surgery for sterilization. This case raises an important issue: does the patient have the capacity for reproductive decision-making? If such capacity is confirmed, then the patient should be responsible for consenting to the procedure. The authors stressed that the surgeons involved will seek to determine capacity and not competence because competence is a legal determination. Determination of this capacity often cannot be made by a single medical professional, and it can never be made based on one conversation; often, multiple members of the medical team will need to evaluate the patient. The question may not be as simple as "does the patient have capacity currently?" An evaluation of the potential for development of future capacity is also necessary. This process confirms adherence of the medical team to the concepts of autonomy and justice. If the determination is made that the patient currently has capacity to decide, the

patient's decision should prevail. If future capacity may develop, interval arrangements to provide birth control information to the patient may be necessary along with careful follow-up to ensure that the patient's progress and compliance with birth control measures are adequate.

An aspect of informed consent that has current interest involves genetic testing and the potential for certain patients to benefit from genetic counseling, ongoing surveillance, and/or preemptive surgery. This topic is discussed in an article by Lucassen[19] in the *Annals of the Royal College of Surgeons of England,* 2009. The increasing number of genetic tests available has improved the ability to determine the risk of certain diseases. However, when a patient is known to have a genetically determined disease, the surgeon may be faced with the challenge of determining how much information should be disclosed to the patient's family members. Determining the extent of the confidentiality of a patient's information is often a complex process. Patients may express a wish that family members not be told. Courts have not conclusively ruled on the extent of family notification or the instances in which the welfare of family members may require that patient confidentiality be breached. In these settings, extensive communication with patients and other health care professionals will be necessary to determine a path that satisfies the requirements of patient autonomy and the obligation to protect the welfare of relatives. Involvement of a hospital ethics committee may be helpful in these situations.

A final aspect of informed consent relates to decisions made by surgeons, hospitals, and patients to use medications, medical devices, and implants. The choice of a medication or device is often made on economic grounds, with hospitals seeking to stock inventory in a cost-effective manner, and surgeons, at times, seemingly choosing devices based on economic relationships with the manufacturer. Device and drug makers also market directly to patients. These practices raise questions about the responsibilities of surgeons, institutions, manufacturers, and patients during these transactions. This topic was discussed in an article by Luginbuhl and coauthors[20] in *Surgery,* 2010. In the hypothetical scenario presented by these authors, a patient who is to undergo bilateral total knee replacement asks the surgeon to use a joint prosthesis that he has seen advertised. The implant, which is the most expensive available, has also been recommended by his friends. The hospital, however, recommends an implant that is less expensive and is said to be equivalent in functionality and durability. The surgeon is accustomed to using a prosthesis that is intermediate in price—and owns stock in the company that manufactures this particular implant. The representative of the manufacturer of the prosthesis requested by the patient has offered to be present in the operating room to assist the surgeon with the implantation. In this scenario, economic conflicts are present for both the surgeon and for the hospital. The hospital's interest in the prosthesis they recommend is based on the desire to improve revenue; however, a possible ethical rationale for the hospital's recommendation could be based in the concept of justice. If the hospital wishes to reduce the overall cost of a scarce resource, this could be defended as a just action.

The surgeon's conflict is less overt. The surgeon does own stock in the company that manufactures and markets the prosthesis, but the prosthesis is also the one with which the surgeon has the most experience. Because of this experience, the surgeon is familiar with the safe use of the prosthesis and with the results obtained.

The participation of the manufacturer's representative is justifiable if it remains in a purely advisory role.

The interest of the patient is a moral one and is based in the concept of respect for the autonomy of the patient. Despite this, the patient does not have the experience or training necessary to make a fully informed choice. Also important is the concept of beneficence: the surgeon's objective is to provide the safest, most effective care to the patient.

In this situation, the options open to the surgeon are: (1) to accede to the patient's wishes; (2) to use the prosthesis recommended by the hospital; (3) to inform the patient that the surgeon prefers to use the prosthesis that the surgeon is accustomed to; (4) or to refer the patient to another surgeon. The option to pass the decision process and the responsibility of care to another surgeon is an undesirable option. Instead, the surgeon can satisfy the obligation for informed consent by disclosing the stock ownership and suggesting to the patient that the strength of experience and familiarity with the results associated with the use of this prosthesis justify the choice. The patient can then make an informed decision. The decisions

regarding the conduct of the operation and the use of implants and equipment should be made by the surgeon based on experience, training, and knowledge. Ceding this decision solely to the patient would not be a safe or effective option.

Ethical Problems Relevant to Disclosure of Information to Patients

Three articles that provide insights relevant to the ethical issues associated with disclosure of medical information to patients will be reviewed in this section of the overview.

The first article was by Gallagher and coauthors[21] in the *New England Journal of Medicine,* 2007. The authors cited several data sources confirming that harmful medical errors are an important source of patient morbidity and that patients expect to be told if they have been harmed by a medical error. Other data cited by the authors support the conclusion that there is a significant gap between this desire and the actual frequency of reporting errors to patients in medical practice. Several agencies have developed standards for reporting medical errors to patients; the agency that the authors cited is the National Quality Forum. This agency recently added standards for disclosing unexpected outcomes to its list of recommended safe practices. This list is included as an illustration in the article and is reproduced as Figure 3.

Figure 3 Guidance for disclosure of medical information. Reproduced from Gallagher and coauthors[21] with permission.

Key Elements of the Safe Practice for Disclosing Unanticipated Outcomes to Patients.*
Content to be disclosed to the patient
Provide facts about the event
Presence of error or system failure, if known
Results of event analysis to support informed decision making by the patient
Express regret for unanticipated outcome
Give formal apology if unanticipated outcome caused by error or system failure
Institutional requirements
Integrate disclosure, patient-safety, and risk-management activities
Establish disclosure support system
Provide background disclosure education
Ensure that disclosure coaching is available at all times
Provide emotional support for health care workers, administrators, patients, and families
Use performance-improvement tools to track and enhance disclosure

* Data are from the National Quality Forum.

Published studies have supported the conclusion that effective error reporting systems reduce the risk of malpractice litigation. Despite the availability of these data, the adoption of error reporting protocols in institutions has been variable, and there are few studies on the impact of reporting. Gallagher and colleagues emphasized the importance of viewing error reporting as a patient safety issue rather than as a risk management matter. They further pointed out the need to train health care providers in effective techniques of error reporting in order to achieve competence—necessary components of the error reporting conversation include a clear presentation of the facts about the event, including evidence of an error causing the event, an expression of regret for the unanticipated outcomes, and an apology if an error caused the outcome. Data on the outcomes of disclosure conversations need to be gathered and analyzed. One successful disclosure program is described by Gallagher and coauthors: this program includes no-fault compensation for patients' out-of-pocket expenses up $30,000 and disclosure training for physicians and staff (the compensation payments are not reportable to the national practitioner databank).

Additional information relevant to disclosure of adverse events and errors was presented in an article by Lipira and Gallagher[22] in the *World Journal of Surgery,* 2014. The authors offered the opinion that effective programs of error disclosure are critical to patient-centered health care and are fundamental components of patient safety and performance improvement efforts. The authors emphasized that disclosure is also an important factor that supports patient autonomy. Barriers to effective disclosure include surgeon concerns that disclosure may be interpreted as admission of fault. Surgeons are also often concerned that acknowledging a patient's distress that is caused by disclosure could make the patient feel that the event was more serious than described; however, if disclosure is not offered or is only partially done, surgeons risk appearing cold and uncaring. To deal with these barriers, the authors recommended institution-level programs for teaching disclosure techniques, involvement of all members of health care teams, and meticulous gathering of data to determine outcomes of disclosure efforts.

The final article discussed in this section of the overview was by Moffatt-Bruce and coauthors[23] in *Annals of Thoracic Surgery,* 2014. This article is supplied as a full-

text reprint accompanying some formats of *SRGS*. The authors presented a case involving an error made in the surgical care of a patient that resulted in a complication that was cared for by a second surgeon. The second surgeon discovered that the likely cause of the complication was an inappropriate operation performed by the first surgeon. The first surgeon is encouraged to disclose the error to the patient, but refuses—this forces the second surgeon to then struggle with whether or not to disclose the error to the patient. In the discussion of this case by two experts, the consensus is that the patient should be informed, but the exact means vary among the discussants. Honest disclosure is important, but often, it is difficult to arrive at an accurate determination of the type of error and its contribution to the subsequent complication. This is because of the complexity of ascertaining key facts, such as the information that was provided to the patient by the first surgeon, the exact sequence of events, and the presence of confounding factors. The consensus at the conclusion of the discussion was that the second surgeon should obtain advice and guidance from senior leadership in the institution in order to determine a fair and ethical means of informing the patient of the error and its possible effects on the patient's subsequent state of health.

Ethical Dilemmas Related to Medical Malpractice Litigation

The single article reviewed in this section of the overview was by Ferreres[24] in the *World Journal of Surgery,* 2014. The author opened the discussion by stressing that the surgeon who serves as an expert witness in medical malpractice litigation will be articulating the standard of care relevant to the clinical situation under consideration during the proceedings; because of this, the surgeon-witness should bring the same level of ethical commitment to this duty as they bring to the clinical practice of surgery. The litigation process will usually require that the witness be a licensed health care professional and, preferably, board certified in the specialty most relevant to the litigation in question. Several medical professional organizations, including the ACS and the AMA, have issued statements describing the responsibilities and qualifications of expert witnesses; the ACS statement is available on the ACS web site at *www.facs.org*.

One of the major obligations of the expert witness is to articulate the standard of care for the incident in question and to provide information that will distinguish between substandard care and an unfortunate outcome that was not influenced by the level of care provided by the defendant. Specific information provided by the expert witness should confirm whether or not the defendant acted according to accepted standards of care; in addition, the testimony should confirm whether or not actions by the surgeon caused harm to the patient. It is critical that the testimony be characterized by integrity, honesty, impartiality, justice, confidentiality, respect, equality, and transparency. Data relevant to the case will need to be evaluated systematically, objectively, and dispassionately, without regard to the consequences to either side. Similarly, ethically sound expert witness testimony will, according to the author, be objective and truthful without concern for the outcome of the litigation. Failure to provide adequate expert testimony usually results from failure to present satisfactory evidence to support a conclusion that the expert witness has sufficient understanding of. The author recommended that professional societies review and evaluate expert witness behavior to be certain that testimony is free of any deceit, that the witness was competent to supply information relevant to the case, that the testimony was free of bias and manipulation, and that there were no conflicts of interest.

Ethical Challenges in Surgical Innovation

In an earlier section dealing with informed consent, we reviewed data relevant to assessing patient understanding and providing adequate information to help fully enable patient autonomy and shared decision-making. In this section of the overview, articles will be reviewed that deal with surgical innovation: surgical innovation, for the purposes of this discussion, will include the introduction of new techniques, care processes, and technologies into surgical practice.

In the *World Journal of Surgery,* 2014, Miller and coauthors[25]stated that innovation is always associated with a degree of uncertainty. While surgeons considering the introduction of a new or modified procedure may be optimistic about the procedure's benefits, there will always be unknown consequences that are clinically significant.

Two examples of procedures that were introduced with significant potential for improving patient outcomes were jejuno-ileal bypass for morbid obesity and laparoscopic cholecystectomy. The long-term consequences of jejuno-ileal bypass were not known when the operation was introduced. Over a short-term period, the procedure resulted in significant weight loss, but in the long term, there were serious and often life-threatening complications such as liver damage and nephrolithiasis. When laparoscopic cholecystectomy was introduced, there were early benefits in terms of shorter intervals of reduced activity and shorter hospital lengths of stay. A significant period of time passed before sufficient data were available to confirm that the procedure was associated with a risk of common bile duct injury that was 15 times higher than for open cholecystectomy.

The authors noted that unknown factors raise ethical challenges because of the need to obtain informed consent from patients. One useful approach to quantifying risk is to provide information on risk of complications for other, similar operations. The authors described an approach used at their institution: patients considering donation of a portion of their liver for transplantation were given information regarding risks and benefits of similar operations such as segmental liver resection for liver neoplasms.

Another ethical challenge in obtaining informed consent is the optimism bias that influences the thinking of both the patient and the surgeon. It is tempting for the patient to believe that the newer procedure is bound to be better than the old one, and descriptions of risk and benefit are viewed from the perspective of this bias. For the surgeon, there is frequently investment of time and effort in developing the procedure and there may be financial involvement as well. These factors not only impact the informed consent process, but also pose threats to professionalism. In this situation, minimizing any potential conflict of interest is necessary. Careful consideration of the power these biases have to produce a lack of objectivity during the informed consent process is critical to avoiding the ethical pitfall of inadequate consent.

Moffatt-Bruce and coauthors also stressed the potential cost factors that may be involved in introducing innovations into surgical practice. A good current example is the introduction of robotic surgery. This innovation has significant potential, but is associated with major up-front costs for equipment and training. Data cited by the authors confirm that outcomes of robotic surgery for some procedures may not justify the costs incurred in introducing the new technique.

Miller and colleagues[25] emphasized the importance of obtaining accurate patient outcomes data so that the human and financial costs of an innovation can be known. One way to obtain a large enough volume of patient data to permit a judgement on the value of an innovation is to enter data into a validated and carefully monitored patient dataset. Requiring that a third-party data manager (who is objective or possibly blinded to the sources of the data) monitor and interpret the outcomes will serve to reduce the risk of bias and inaccurate data.

Strong and coauthors[26] also dealt with the ethics of surgical innovations in *Surgical Endoscopy,* 2014. This article considered a group of important questions:

1. How is the safety of an innovation ensured?
2. What is the timing and the process of introducing the innovation?
3. How are patients informed before the innovation is used?
4. How are surgeons trained and credentialed in the new technique?
5. How are outcomes tracked and evaluated?
6. How are responsibilities to patients and society balanced?

The authors noted that the process for introducing new drugs into the United States market, a process controlled by the Food and Drug Administration (FDA), has proven to be costly and has resulted in many potentially beneficial drugs and devices being marketed outside the United States. The FDA does not control the introduction of new technologies or techniques and surgical innovations are not required to provide the same level of protection to patients as is provided in research studies. The authors identified several professional organizations that provide guidance on validating the value of new techniques; the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) produces practice guidelines and has created a Technology and Value Assessment Committee. Data cited in the article confirmed that these efforts do not affect the process of introducing an innovation into a local institution or the credentialing

of clinicians. For this, the authors recommended that hospital administrative and clinical leadership form "new technology committees" that would be charged with the responsibility of developing a process for introducing new practices and technologies into the local institution. The authors also cited data supporting the use of simulation as a component of the training and credentialing process for the introduction of new technologies or techniques.

Additional perspective on the ethical issues associated with surgical innovation was presented in two articles: the first of these was by Biffl and coauthors[27] in the *Journal of the American College of Surgeons,* 2008. This report is a description of the position statement by the Society of University Surgeons regarding the ethical development and application of surgical innovations. The authors indicated that a surgical innovation is a planned or unplanned use of a procedure or technique that differs from currently accepted practice. Examples of both planned and unplanned innovations were provided: a planned innovation is the use of natural orifice transluminal endoscopic surgery to remove an appendix transvaginally; an unplanned innovation would be determined by an intraoperative situation that arises without prior expectation and requires an innovation to solve the problem. An example of an unplanned innovation that later evolved into accepted practice is the use of damage-control surgery for critically injured trauma patients. The authors recommended that preoperative informed consent include a complete discussion of the risks and benefits anticipated from the use of the planned innovation. When an emergency dictates the unplanned use of an innovation, this should be discussed with the patient and any surrogates charged with protecting the patient's interests. This discussion should begin as soon as possible after the operation and may involve several conversations. Institutional representatives and other caregivers may need to be involved. Approval by an institutional review board is required if the innovation is planned and the experience will be used to publish clinical research findings.

The authors stressed that off-label use of drugs and medical devices may require reporting the usage to government agencies. Off-label drug usage of requires complete descriptions of potential risks to patients and surrogates.

Overall, the article by Biffl and coauthors is a valuable overview of matters relating to the development of surgical innovations.

Surgeons are also challenged with considering the ethical implications of innovations already in use. Frequently, these innovations are attractive to surgeons and to patients but have not been fully evaluated for effectiveness. The question that arises is: what should the surgeon do until the innovation is shown to be beneficial? Examples of such innovations include the surgical robot, single incision laparoscopic procedures, and natural orifice transluminal endoscopic operations. A description of a thought process for solving these challenges was presented in an article by Angelos[28] in *Surgical Clinics of North America,* 2009. The author began by noting that the fundamental legal question related to the use of new techniques in surgical practice is the definition of "standard of care." Failure to adhere to the standard of care is the legal definition of medical negligence. The author argued that there is no clear evidence to support the claim that recurrent laryngeal nerve monitoring decreases the risk of recurrent laryngeal nerve injury. Therefore, even if most surgeons used monitoring, it would not meet the requirements for becoming the standard of care. Angelos also explained that the main ethical consideration related to the use of recurrent laryngeal nerve monitoring has to do with the presentation of honest information to patients; Angelos pointed out that some surgeons promote the use of the monitor as a key to lowering recurrent laryngeal nerve injury risk. Ethical behavior, he stressed, requires that the surgeon present a balanced and scientifically valid explanation to the patient. Openly claiming that using the monitor reduces risk is, therefore, unethical.

Ethical Issues in Organ Transplantation

Surgeons caring for patients who are candidates for organ transplants encounter frequent ethical problems; this is not surprising, given the fact that transplant surgeons face and make difficult decisions regarding the just distribution of a number of transplantable organs that is far fewer than the number of patients who would potentially benefit from an organ transplant. Freeman and Bernat[29]provided an overview of the multiple ethical considerations involved in organ transplantation in *Progress in Cardiovascular Dis-*

eases, 2012. The authors reviewed several topics relevant to the application of surgical ethics principles when caring for transplant patients. The first topic discussed was the need for resolution of the apparent conflict between the need to do what's best for the individual patient and the need for stewardship of a scarce resource: the transplantable organ. The process of resolving the stewardship conflict needs to be transparent and patient-centered. The authors noted that this conflict often arises when the treating physician is faced with a decision to begin organ support efforts to maintain patient life while a transplantable organ is sought. It is essential, according to Freeman and Bernat, that the treating physician or surgeon be involved in this process. Two approaches to addressing the stewardship conflict are to use patient-based measures, such as those used in allocating liver allografts, or to use an allocation committee, such as the type employed for decisions regarding allocation of cardiac allografts. The main ethical principle at work in the allocation of scarce organs for transplantation is the principle of justice: Distributive justice means that the scarce resource should be allocated fairly to the population in need; Compensatory justice means that injured persons should receive rewards that are proportional to the severity of the injury. Another form of compensatory justice is the awarding of an advantage to an individual in return for a willingness to accept greater risk. In the field of cardiac transplantation, centers may allocate organs deemed to be at high risk for failure or complications to individuals who are in dire need of a transplant and are willing to accept the higher risks associated with use of these organs.

An additional ethical challenge described by the authors focuses on the problem of retransplantation: should a recipient who willingly accepted a higher risk organ receive a higher priority for retransplantation should the organ fail? This problem can be addressed using the ethical concept of utility. The authors noted the application of this concept in the form of "transplant benefit," an assessment that takes into account the outcome of the transplant procedures as well as the outcomes of patients who remain on the waiting list. This approach permits application of a measure of benefit for all patients who are candidates for transplantation, not just those who receive an organ. Freeman and Bernat acknowledged that such a system tends to allocate organs to recipients who are likely to progress after a transplantation procedure, and offers other approaches, such as implantable ventricular assist devices, to patients on the waiting list who are not as likely to survive and do well post-operatively.

Another ethics-related topic relevant to the discussion of organ allocation was discussed in an article by Shafran and coauthors[30] in the *World Journal of Surgery,* 2014. The authors noted that the concept of triage has governed most organ allocation plans; this concept seeks to provide the greatest good for the greatest number of people in need. In their article, the authors included the list of guiding principles for organ allocation used by the United Network for Organ Sharing (UNOS). The goal of these principles is to maximize the availability of organs for donation and allocate the available organs based on medical criteria that rely on the concepts of net medical benefit and justice that were discussed previously. The principles emphasize the need to provide transplant candidates a reasonable opportunity for transplantation within time intervals that are similar in various regions of the country.

Shafran and coauthors also discussed a controversial approach to increasing the organ supply—the sale of organs. There are strong arguments offered in the article that support a closely monitored system of sales that would increase organ availability while minimizing the risk of donor abuse and transmission of disease. A national program for donor compensation exists in Iran and has resulted in reductions in that nation's kidney waiting list. Some ethical experts have argued that organ sales violate human dignity, but other experts have asserted that dignity is determined by attitudes and behaviors, not the use of organs.

Additional perspective on the use of related and nonrelated donor organs was presented in an article by Testa[31] in the *World Journal of Surgery,* 2014. The author indicated that ethical conflicts arise when it is necessary to "harm" a living donor in order to provide a viable organ for a needy recipient. This conflict is settled using "double equipoise," which is an approach that seeks to minimize risk to the donor while maximizing benefit for the recipient. The author emphasized the importance of a patient-centered approach to potential donors that does not include any evidence of "pressure" to donate. Cited

data support the fact that the overwhelming majority of donors did not feel pressured to donate. While it is desirable that donors receive a complete explanation of risks and benefits associated with the procedure, it is understood that "complete explanation" is a relative term, since full understanding of all risks and benefits is rarely achieved. Ethical approaches to this problem include a commitment by transplant physicians and surgeons to do their best to explain risks and benefits to patients and family members, recognizing that this explanation may require more than one session, and that there may be limitations to complete understanding.

Testa also reviewed concepts central to the sale of organs. Data cited in the article support the need for a closely monitored system, as described previously. These data indicate that in some less industrialized nations, payment benefits for organ donation were not made available to the donor. Supporters of a monitored system of organ sales contend that the system would correct this inequity.

Donor death was the final transplantation topic discussed in the article by Freeman and Bernat.[29] They stated that brain death has been interpreted as absence of all evidence of responsiveness, absence of brain stem reflexes, and complete apnea in the presence of an irreversible structural brain lesion and no potentially reversible conditions. If these conditions cannot be confirmed by neurological examination, brain imaging to document absence of cerebral blood flow may be added. Freeman and Bernat noted that the American Academy of Neurology has removed the requirement of a second neurological examination. The authors emphasized the fact that brain death determination guidelines need to incorporate adjustments for the use of therapeutic hypothermia in patients who have sustained cardiac arrest; there are at least two documented instances where brain death criteria were fulfilled in patients treated with hypothermia, but both patients recovered some brain function.

Freeman and Bernat also discussed the use of circulatory death determinations. Important issues related to this approach include the duration of absence of circulatory function before the declaration of donor death and the types of organ support that can be used to restore some circulatory function after the declaration of death.

The authors' final topic related to donor death was the "dead donor rule," which states that the donor must be declared dead so that the procedure used to harvest organs cannot cause the donor's death; this rule has been adopted by government at the federal and state level as well as professional transplant societies. Ethics publications, however, have criticized the dead donor rule, contending that a donor who cannot survive and who has given consent (or family members have given consent) for donation should be allowed to undergo the organ harvest procedure. This argument has been rejected by both government and professional agencies involved in organ transplantation.

Ethics & Global Surgery

In 2014, the Lancet Commission on Global Surgery began an effort to quantify needs and identify useful interventions for provision of necessary surgical care in low- and middle-income countries. The Commission report was presented by Meara and coauthors[32] in *Lancet,* 2014. The report stated that mortality rates for common, easily treated conditions are high in regions that do not have surgical care available. These conditions include appendicitis, hernia, fractures, obstructed labor, and breast cancer. At the time of publication, data cited in the report confirmed that nearly five billion people worldwide did not have adequate access to surgical and anesthetic services. Additional data suggested that an additional 143 million surgical procedures were needed each year in order to bring adequate surgical care to underserved areas. At the time the report was published, only six percent of surgical procedures each year were performed in underserved areas; the greatest unmet needs were in Africa and southern Asia. In addition, 33 million people annually face catastrophic expenses for needed surgical and anesthetic care. The report concluded that provision of needed care was feasible and economically possible, and suggested that providing such care be included in the list of indispensable global health care services. The recommendation was supported immediately by the World Bank and the World Health Organization (WHO).

A statement of support for plans to provide essential anesthetic and surgical care in underserved areas was presented in an article by Botman and coauthors[33] in the *World Journal of Surgery,* 2015. The authors recommended that organizations such as the World Bank, WHO, the United Nations, the governments of all nations, and all of the professional medical and surgical societies and colleges join in an effort to fund and provide essential surgical services in underserved areas of the world. The authors further recommended that essential surgical services be specifically referenced in listed services provided by all government health insurance programs. An essential component for success in this effort mentioned by the authors was a plan to train local health care providers so that a durable means of providing essential surgical services could be developed. Along with the necessary training, the authors recommended that essential equipment be provided. A necessary component of a successful effort would be the development of protocols for ethical, effective, and safe surgical practices that could be implemented in areas of need. This could be accomplished through collaboration among all stakeholders. The authors concluded the article with a strong statement of support for the expected World Health Assembly resolution supporting the inclusion of surgical and anesthetic services among the essential health services provided for all of the world's population.

Additional perspective on necessary approaches for providing essential surgical services was presented in an article by Henry and coauthors[34] in the *World Journal of Surgery,* 2015. Based on assessment of needs and projected availability of physician and nonphysician providers, the authors compiled a list of 15 essential surgical procedures: these included acute management of traumatic injuries (airway, chest decompression), management of obstructed labor and uterine rupture (caesarian section, hysterectomy), management of acute abdominal conditions (cholecystectomy, splenectomy, lysis of adhesions), burn management, amputation, club foot repair, and hernia repair/hydrocelectomy. The authors presented data indicating that training both physicians and nonphysician providers in these procedures resulted in improved outcomes of surgical disease in underserved areas. A similar set of observations in a single community in India was presented in an article by Gawande[35] in the *Lancet,* 2015. The author related a personal experience that included observation of the practice of a single health care provider in India. When simple equipment such as chest tubes and pulse oximeters were made available, emergency resuscitations and general anesthesia became possible; this attracted surgeons and obstetricians to the community, resulting in improved outcomes for common diseases. The practitioner made a special effort to treat snakebite injuries that were common in the community. When local donors were convinced to provide financing for adequate supplies of antivenin, mortality from snakebite injuries improved markedly. The author emphasized that these are convincing examples of how health care outcomes can improve significantly following the implementation of simple, inexpensive interventions.

Embarking on an effort to solve global health problems will inevitably present some ethical challenges. These can be on a geographic level and primarily involve ethical challenges related to natural and manmade disasters or epidemics; ethical challenges can also be encountered on a micro or local level when improved health care is brought to an underserved area with cultural differences, as providers attempt to adjust attitudes regarding ethical practice. A conceptual framework for global health ethics was presented in an article by Stapleton and coauthors[36] in *Global Health Action,* 2014. The authors present a framework of global health ethical issues that included a consideration of the moral significance of health. They stated that good health limits suffering, but also enhances function and extends the range of opportunities offered to individuals. This understanding leads to the conclusion that "justice" in global health terms is most likely to be realized if "health" for the world's population was sought with the intent of providing everyone with a fair opportunity to attain their full health potential; no one should be disadvantaged from achieving this potential if it can be realistically obtained. The authors cited data supporting the concept that if it is possible to help others at minimal cost to ourselves, then we have a moral duty to help. The authors also acknowledged that high priority issues in global health ethics include addressing inequities in distribution of water, food, and housing. There is also a need to address the "brain drain" that occurs when talented people leave a nation to pursue life

in a more prosperous area. The authors emphasized that addressing all of these inequities is an important goal of global health initiatives.

The final topic considered in the article was ethical challenges associated with global health research. The authors contended that research on the prevention of injury and infectious disease in underserved areas had been paid insufficient attention, and that prior research has unfairly benefited developed nations. Newer approaches to research should prioritize a more open research market that would focus on the types of studies that would a) have the greatest impact on global health, and b) whose benefits would be directed to areas of greatest need. The authors also argued that there has been ethical misconduct in projects performed in underserved areas, and that this form of abuse needs to be addressed. They recommended emphasizing respect for all people, respect for autonomy, protection of individuals with impaired or diminished autonomy, and provision of justice insofar as possible.

An article that provided perspective on the moral imperative for academic surgery to support efforts in improving the availability of surgical care to underserved areas of the world was by Schecter[37] in *JAMA-Surgery,* 2015. The author hypothesized that global academic surgery is a subset of global surgery that emphasizes the training of surgical educators and the discovery of new knowledge that leads to correction of global disparities in the provision of surgical care. He noted that the primary reason for global surgery disparities is poverty; thus, efforts to correct this condition need to go hand-in-hand with educational and research efforts in surgery. Schecter emphasized the fact that correcting surgical care inequities on a global level requires not only trained surgeons and nonsurgeon providers, but equipment and materials for anesthesia services, imaging, radiotherapy, and chemotherapy. The author then cited progress in several underserved areas, realized through the collaboration of several academic departments of surgery with one or more educational institutions in an underserved area. This type of effort has resulted in a steady supply of surgical faculty and trainees from well-developed nations to underserved areas. This boost in medical staff has subsequently led to improvements in levels of training, availability of surgical care, and health care outcomes. Schecter described an effort by a collaborative developed by the Pacific Coast Surgical Society as a prime example of a successful program, and stressed that these efforts need to go forward simultaneously with efforts to improve economic productivity and political stability in underserved areas—providing well-educated surgical-care providers could help produce individuals who could also assist in these areas.

Military Medical Ethics

Significant medical ethics challenges are associated with service in the military and in the medical treatment of combatants and civilians. Reports of participation by physicians in acts of torture at the Abu Ghraib and Guantanamo Bay prisons represent additional areas where medical ethics principles were violated. Gross[38]provided perspective on these issues in the *Cambridge Quarterly of Medical Ethics,* 2013. The author noted that members of the military services are subject to restrictions of their autonomy, privacy, right to informed consent, and right to refuse treatment; statements of patient rights that are posted in military medical facilities remind service members of this fact. Because national security is not subject to a medical decision process, patient rights can be infringed upon for nonmedical reasons. Physicians serving in the military may be forced to violate patient confidentiality or withhold information from patients because the particular needs of military service may temporarily override patient rights. Ethical considerations also enter into decisions to perform human testing of toxicity of proposed chemical weapons; these tests do not offer any hope of benefit to the participant. Testing of investigational drugs or vaccines, by contrast, do offer hope of benefit to the research participant. Several instances where participants' rights were ignored during testing of chemical weapons have been recorded. Current guidelines require that testing of items such as protective clothing be done only with informed consent and confirmation of the participant's right to end an experiment. Data from prior animal experiments that support the safety of the agent(s) being tested and medical supervision of the experiments are also required.

Disparities in providing treatment to patients in combat zones have been recognized. In Iraq and Afghanistan, the military trauma system rapidly evacuates most American military patients to hospitals in Europe and the United States. This multi-layered system is very advanced

and associated with improved outcomes. However, while access to sophisticated, multi-level care is required for injured children and for prisoners of war, this system of care is not available to host-nation military personnel who may fight alongside American forces, or to indigenous civilians who may be injured during combat operations—even though these civilians may receive initial treatment in American facilities. This disparity has produced frustration and criticism of the ethical basis of this situation. Ethical issues also arise when treatment of injuries is delayed or prevented because the care facility or transport system is suspected of aiding terrorists.

Gross discussed the ethical issues that arise in situations where torture and forced feeding are used. Statements by professional societies such as the AMA support the right of medical personnel to refuse to participate in these activities; these statements also require medical personnel to report observed ethical breaches. The author brought up the fact that criticism of enhanced interrogation techniques used at Guantanamo Bay were met with derogatory statements directed at those who criticized the torture techniques. Two major ethical questions arose: first was a question of the ethical legitimacy of the torture techniques, while the second question dealt with the propriety of participation in the torture by medical professionals. Enhanced interrogation techniques have been defended on the basis that the information gained may save many innocent lives. The additional position taken was that medical professionals advising the interrogation teams were not caring for the prisoner, but were instead serving as advisors to the interrogation teams. Most ethics experts have supported the right of medical professionals to withdraw from activities they interpret as unethical.

The discussion presented by Gross disclosed several ways to interpret the ethical responsibilities of medical professionals who are serving as military personnel. Some ethicists have provided strong ethically based arguments supporting the participation of medical professionals in caring for wounded combatants, as well as their participation in enhanced interrogation and forced feedings. These and several additional topics were discussed and readers are encouraged to review this material in its entirety.

Patient Safety in Surgical Practice

The landmark report from the Institute of Medicine (IOM) of the National Academy of Sciences, To Err is Human,[39] was completed in 1999 and published in 2000. That report provided data showing that nearly 100,000 deaths occurred each year in the American health system because of medical errors. This report stimulated initiatives to improve patient safety that are ongoing; these patient safety initiatives will be the focus of the articles reviewed in this section of the overview.

Patient Harm: The Magnitude of the Problem

Recent studies have suggested that patient harm due to medical errors occurs more frequently than reported in the IOM report mentioned earlier. One such study was by Classen and coauthors[40] in *Health Affairs,* 2011. This article is included as a full-text reprint accompanying some formats of *SRGS*. The authors used three methods for detecting medical errors using data from three separate hospitals. The detection methods used included voluntary reporting, the Agency for Healthcare Research & Quality patient safety indicators, and the Institute for Healthcare Improvement Global Trigger Tool. The authors noted that there has been ongoing debate regarding the best method of detecting harm due to medical errors. Most reports have relied on self-reported data. These reports focus on "sentinel events": events that cause patient harm, but that are not related to the expected course of the patient's illness. Reviews by national agencies have shown that these "self-report" approaches miss a significant number of harmful errors, which has led to the development of other means of detecting patient harm, including the patient safety indicators and the Utah/Missouri Adverse Event Classification. These methodologies use analyses of discharge diagnostic codes to identify adverse events that may have been caused by medical error; however, these approaches have also been shown to lack sensitivity and specificity for detection of medical errors. The Global Trigger Tool uses trained health care professionals (usually nurses or pharmacists) to review medical records to detect

"triggers." These could include medication stop orders, abnormal lab results, or use of an antidote medication. Detection of a trigger leads to a complete review of the record and final approval by a physician. The study by Classen and colleagues reviewed 795 records to compare the effectiveness of the global trigger tool to other, more commonly used methods. The global trigger tool detected 90.1% of the medical errors that caused harm (N=393), while the other tools detected 1% and 8.9% of errors respectively. The overall frequency of adverse events detected was unexpectedly high; however, the authors noted that the global trigger tool used a more liberal definition of adverse events than other methodologies. Notwithstanding this fact, the data suggest that adverse events continue to be frequent in the American health care system, despite increased interest in detecting and preventing such events.

Another study that assessed temporal trends in patient harm due to medical errors was by Landrigan and coauthors[41] in the *New England Journal of Medicine,* 2010. The authors conducted a retrospective review of admissions to a random sample of 10 hospitals in a single state. One hundred admissions per quarter were selected and the records of these patients were examined by trained nurse reviewers using the Global Trigger Tool. Suspected harm events detected by nurse reviewers were then re-reviewed by physician reviewers. More than 2,300 admissions were reviewed and the rate of harmful events was 25.1%. The authors found no significant improvement in rates of harmful events over the course of the study interval. The authors noted that the rate of harm events continues to be high and improvement is lacking. They also cited data showing that the penetration of practices to reduce harmful events has been small and the lack of implementation of evidence-based efforts to reduce patient harm may explain, at least in part, this lack of improvement.

Predicting Hospital Safety & Quality

The first study reported in this section of the overview sought to determine whether hospitals that were high performers on mortality for publicly reported harm events due to medical error were also high performers on composite 30-day mortality scores for common medical and surgical conditions. The article was by McCrum and coauthors[42] in *JAMA-Internal Medicine,* 2013. They analyzed national Medicare data for 2,322 acute care hospitals. Nearly seven million admissions were reviewed. The analysis showed that high-performing hospitals on mortality for publicly reported harm events were statistically more likely to be high performers on composite mortality scores. High performance was only weakly related to hospital size and whether the hospital was a teaching facility. The authors concluded that hospital performance on publicly reported events could be used as a surrogate indicator of overall hospital mortality.

The use of composite scores for evaluating hospital performance was validated in a study by Dimick and coauthors[43] in *Health Services Research,* 2012. The authors used Medicare data from 2005 to 2006 to develop composite scores that included hospital caseload volume, risk-adjusted mortality rates for selected procedures, and risk-adjusted mortality rates for associated procedures. Hospitals were ranked according to performance into three groups (bottom 20%, middle 60%, and upper 20%). Data from 2007 to 2008 were used to determine how accurately the earlier scores predicted future performance. The data analysis showed that mortality risk for procedures such as esophagectomy, pancreatectomy, coronary artery bypass, and aortic valve replacement varied significantly based on hospital ranking group. The composite scores were effective at predicting future performance. The authors noted that predictors of hospital performance, such as hospital volume and performance on the Surgical Care Improvement Project (SCIP) indicators, have been shown to lack sensitivity and specificity for predicting hospital performance. Data suggested that the composite scores that the authors developed have potential for being accurate predictors of overall hospital performance and may provide a statistically valid approach for ranking hospitals. The authors acknowledged that their scores were valid for mortality prediction and were, therefore, different from composite scores such as those developed by the Center for Medicare and Medicaid Services and the Society of Thoracic Surgeons, which aim to predict quality in multiple domains and not mortality. The authors cautioned that mortality prediction is useful for

commonly performed procedures such as coronary artery bypass, but less accurate for uncommon procedures such as esophagectomy.

An important component of methods for predicting hospital quality and safety are risk adjustment methodologies that can be used to strengthen the validity of outcome comparisons. Steinberg and coauthors[44] compared two risk adjustment methodologies: University Health System Consortium (UHC) and the American College of Surgeons National Surgical Quality Improvement Program (NSQIP). The article appeared in *Surgery,* 2008. The authors matched 120 medical records that had been subjected to risk adjustment by both methodologies. The data analysis showed that discordance ranged from 5% to 15% in the reporting of medical conditions such as hypertension, diabetes, pulmonary disease, and cardiac disease when the two systems were compared. The overall frequency of associated medical conditions was similar when the two systems were compared. The largest difference was observed in the reporting of postoperative complications. The NSQIP methodology reported complications in 28% of patients, while the UHC system reported complications in only 11% of patients. The difference was even more striking for the reporting of surgical site infections: NSQIP reported this complication in 13% of patients, while UHC reported it in only 1% of patients. The authors emphasized the fact that the UHC system differs significantly from the NSQIP system; UHC uses DRG data that are generated postdischarge, while the NSQIP system uses trained nurse reviewers to review records to determine risk and outcomes. These data were presented to the plenary session of the 2008 meeting of the Central Surgical Association. In the discussion that followed the presentation, it was stressed that there are distinct differences between outcomes data reported from administrative data and outcomes data from direct medical record reviews performed by a health care professional. These differences probably are linked to the discrepancies noted by these authors in detection of clinically significant outcomes.

From the data presented in the previous articles, it is evident that using single data sources to predict hospital quality is potentially hazardous. This has led to the use of composite measures, some of which have been discussed in earlier reviews. An article that focused on the hazards of using single data sources to predict quality was by Krell and coauthors[45] in *JAMA-Surgery,* 2014. The authors analyzed data from the NSQIP database for patients undergoing colon resection, pancreatic resection, laparoscopic gastric bypass, ventral hernia repair, abdominal aortic aneurysm repair, and lower extremity revascularization. The data included outcomes of more than 55,000 patients. The authors conducted reliability tests on the outcomes data and determined that reliability depended strongly on caseload volume and the frequency of the outcome event. Reliability for assessment of overall morbidity was achieved for pancreatic resection, laparoscopic gastric bypass and colon resection, but reliability was not reached for any severe morbidity or mortality. The authors recommended that 100% of a hospital's caseload be assessed for outcomes to improve reliability and that statistical methods be used to improve reliability when determining risk-adjusted outcomes for infrequent events.

Lawson and coauthors[46] focused on the use of composite measures for evaluating hospital quality in *Annals of Surgery,* 2016. The authors noted that some hospitals are reluctant to participate in risk-adjusted clinical registries because of expense. In such hospitals, claims data may be utilized to estimate hospital quality. In this study, the authors sought to determine whether the use of a hybrid model included data from claims as well as clinical registry data. The authors used data on nearly 112,000 patients from 206 hospitals, and found, as have other investigators, that agreement between claims data and clinical registry data was poor. This is likely due to the fact that claims data are gathered primarily for billing purposes, while registry data are gathered for the purpose of accurately identifying outcomes, especially complications. The data analysis reported in this article showed that use of administrative claims data to identify outcomes and clinical registry data to identify complications had the best agreement on assessments of hospital quality.

Readmission Rates & Hospital Quality

The single article reviewed in this section of the overview was by Tsai and coauthors[47] in the *New England Journal of Medicine,* 2013. The authors stated that government, payers, and other interested parties have been increasingly interested in using readmission rates within thirty

days of discharge as a measure of health care quality. Hospitals with readmission rates for certain medical diagnoses that are deemed higher than desirable are subject to financial penalties. Use of readmission rates has been controversial. Data cited by the authors indicate that hospital readmission rates for medical diagnoses frequently do not correlate with other measures of hospital quality. Other data have shown that hospitals that care for the sickest and poorest patients often have the highest readmission rates, suggesting that social and clinical factors contribute to readmission rates more than low-quality care. The authors stated that readmission data after surgical care has not been studied, and their report provided results of an analysis of Medicare data for patients who had undergone coronary artery bypass, pulmonary lobectomy, endovascular or open repair of abdominal aortic aneurysm, colectomy, and hip replacement. Thirty-day readmission rates were examined and correlations with other accepted measures of hospital quality were determined. Nearly 500,000 discharges were analyzed. The median risk-adjusted readmission rate was 13.1%. Hospitals with larger caseload volumes and higher indices of performance on other hospital quality measures had significantly lower thirty-day readmission rates. Higher hospital mortality rates were associated with increased risk for readmission. The authors noted that these data support the conclusion that readmission for surgical patients differs from medical patients. While medical patients may be readmitted because of lack of social support or lack of access to primary care, surgical patients are more likely to be readmitted because of a surgical complication. The authors concluded that readmission rates may be a valid means to determine the quality of hospital care for surgical patients.

Malpractice Litigation & Quality of Surgical Care

Concern over the devastating effects that malpractice litigation has on the professional and personal lives of surgeons has stimulated persistent efforts to accomplish "tort reform." The central message of tort reform has traditionally been to minimize malpractice litigation that is based on marginal/lack of hard evidence of medical negligence. Data on malpractice litigation shows that frivolous lawsuits rarely result in compensation to patients. Other costs are present, however, and these include the direct costs of defending the malpractice claim and the emotional distress that is associated with the process of defending the claim. Studdert and coauthors[48]presented data on malpractice claims and payments in the *New England Journal of Medicine,* 2006. This article is included as a full-text reprint accompanying some formats of *SRGS*. In this study, trained physicians reviewed 1,452 randomly sampled closed malpractice claims from five liability insurers. The analysis showed that 3% of claims had no verifiable medical injuries and 37% did not involve errors. Seventy-two percent of claims that were not associated with errors or injuries did not result in compensation to the plaintiff, while 73% of claims that involved errors or injuries did result in compensation. The analysis also showed that nonerror claims were more likely to go to trial than to be settled. When plaintiffs did receive compensation for nonerror claims, the compensation amount was significantly lower than for compensated claims that involved errors. The authors concluded that the frequently heard description of the malpractice litigation process as being fraught with frivolous claims was not borne out by the data. What was confirmed was the fact that costs of litigation were large, and that eliminating the small proportion of frivolous claims would reduce the cost of litigation by only a small amount. Of interest in the findings was that unpaid claims that involved error or injury were very costly to the plaintiffs. A meaningful effort at tort reform should include a mechanism for compensating patients who suffer an injury due to error. The authors also concluded that the overhead costs of litigation were exorbitant and totaled more than half of the amount of compensation awarded to a patient who suffered injury from an error.

An article that reported data on the specialty distribution of malpractice litigation was by Jena and coauthors[49] in the *New England Journal of Medicine,* 2011. The authors reviewed closed claims for the interval 1991 to 2005 from a single malpractice insurer with a nationwide client base. They reported the proportion of physicians from twenty-five specialty groups who had malpractice claims in a given year, along with the proportion of claims that resulted in payment to the plaintiff and the sizes of the payments. The analysis showed that in each year, 7.4% of physicians

had a malpractice claim. Only 1.6% of claims in a given year led to a payment to the plaintiff; out of all claims, 78% did not result in payments to plaintiffs. The highest risk specialties for malpractice claims were neurosurgery, cardio-thoracic surgery, and general surgery, while the lowest risk specialties were family medicine, pediatrics, and psychiatry. Of interest was that mean payments to plaintiffs were highest for claims against pediatricians. The authors estimated, from the data analyzed, that by the time a physician reaches the age of 65, 75% of those in the low-risk specialties will have experienced a malpractice claim and 99% of those in high-risk specialties will have had a claim. The authors emphasized the fact that physicians can protect themselves against the direct cost of malpractice litigation by purchasing malpractice insurance; however, this insurance does not cover the indirect costs of litigation to physicians, including time, stress, added work, and reputational damage.

Pathways to Improved Patient Safety in the Operating Room

Improving safety in the operating room requires an understanding of how and why deviations of care occur and use of interventions to correct the factors that lead to those deviations. The success of checklists in improving flight safety has led to their increased use in surgical settings. Another approach to improving safety that has been successful in the aviation field has been team training. In this section of the overview, several articles will be reviewed that deal with these topics.

Successful implementation of safety measures requires an understanding of the etiologies and means of recovery from intraoperative care deviations. Hu and coauthors[50] used video recordings of high-acuity procedures to improve understanding of deviations in care processes in *Annals of Surgery,* 2012. This article is included as a full-text reprint accompanying some formats of *SRGS*. The authors opened their discussion by explaining that human factors engineering is a scientific effort to understand the interactions of humans with elements of systems. This area of scientific inquiry has been used to improve safety in complex environments such as nuclear power plants and commercial aviation. Since the operating room is the most frequent site of patient safety events in surgery, and because the operating room is a complex environment consisting of human, physical, and system factors that may influence events, it is a setting where human factors engineering may help improve safety. According to the authors, most retrospective analyses of patient safety events that occur in the operating room, such as root cause analysis and analysis of malpractice claims, are subject to recall bias; to help remedy this, real-time video recordings are used as a means of quantifying the frequency and etiology of patient safety events, as well as identifying ways that these events can be prevented or effectively dealt with. The authors recorded 10 high acuity operations representing 43.7 hours of patient care. Deviations were defined as delays or episodes of decreased patient safety. The analysis showed that there were 33 deviations; one deviation occurred every 79.4 minutes. The etiologies of deviations were most frequently problems of communication or organizational structure. The authors noted that problems of communication may result from inefficient delivery of information and/or incomplete comprehension of a clinical situation. They presented a representative case wherein the magnitude of surgical bleeding was not appreciated by the anesthesiology resident because of incomplete description by the surgeon, lack of availability of supervision from a senior staff anesthesiologist, and reluctance to ask the surgeon for more detailed information because of status asymmetry. Another cause of deviations was failure of coordination. An example of this was the late arrival of the attending surgeon—this caused a significant delay because the junior members of the operating team did not feel comfortable starting the case without the senior surgeon. Failures of coordination also occur when there is uncertainty among team members about issues such as instrumentation and patient positioning. The authors noted that while the etiology of deviations was associated with provider or organizational issues, correcting these deviations was always accomplished by providers. Hu and coauthors recommended that efforts to increase patient safety take into consideration the need for some flexibility for providers to adapt and react, so that the deviation can be effectively corrected. Standardization, thought to be a means of reducing variability and improving safety, will

need to be combined with the recognition that adaptation and action by providers is a necessary means of correcting safety deviations.

The success of checklists in improving aviation safety has stimulated efforts to employ these safety interventions in surgical settings. Potential benefits from the use of checklists were the focus of an article by Haynes and coauthors[51] in the *New England Journal of Medicine,* 2009. This article is included as a full-text reprint accompanying some formats of *SRGS*. WHO's "Safe Surgery Saves Lives" program introduced a safe surgery checklist as a component of its recommended safety interventions. An example of the checklist content is illustrated in the article and reproduced as Figure 4. The checklist consisted of three major parts: The first component is a sign-in, where members of the anesthesiology, nursing, and surgical teams document patient identity, confirm that monitoring devices are functioning properly, make certain that team members are aware of any patient allergy, and confirm that airway risk evaluation has been done and that appropriate blood and fluids are available; The second component is a "time-out" before the incision is made—in this section, all team members are introduced by name and role, patient identity is reconfirmed, and the surgeons and anesthesiologists review the steps of the procedure with the team and make certain that any concerns are addressed. Antibiotic administration and confirmation of the availability of pertinent images are also performed at this stage; The final component is a "sign-out" that occurs before the patient leaves the operating room. In this section, the nurse reviews procedure name, outcomes of any counts, pathology specimen labelling, and key concerns for patient recovery. Any concerns or issues with equipment are also addressed at this time.

The study documented thirty-day death and complication rates in 3,733 patients from eight hospitals before introduction of the checklist and in 3,955 patients from these hospitals after the checklist was introduced. The analysis showed that mortality was reduced from 1.5% to 0.8% and complication rates were reduced from 11% to 7%. Significant reductions in deaths and complications persisted after statistical adjustment for numerous confounding factors. Despite these encouraging outcomes,

Figure 4 Summary of the elements of the WHO Safe Surgery checklist. Reproduced from Haynes and coauthors[51] with permission.

Elements of the Surgical Safety Checklist.*

Sign in

Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that:
- The patient has verified his or her identity, the surgical site and procedure, and consent
- The surgical site is marked or site marking is not applicable
- The pulse oximeter is on the patient and functioning
- All members of the team are aware of whether the patient has a known allergy
- The patient's airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available
- If there is a risk of blood loss of at least 500 ml (or 7 ml/kg of body weight, in children), appropriate access and fluids are available

Time out

Before skin incision, the entire team (nurses, surgeons, anesthesia professionals, and any others participating in the care of the patient) orally:
- Confirms that all team members have been introduced by name and role
- Confirms the patient's identity, surgical site, and procedure
- Reviews the anticipated critical events
  - Surgeon reviews critical and unexpected steps, operative duration, and anticipated blood loss
  - Anesthesia staff review concerns specific to the patient
  - Nursing staff review confirmation of sterility, equipment availability, and other concerns
- Confirms that prophylactic antibiotics have been administered ≤60 min before incision is made or that antibiotics are not indicated
- Confirms that all essential imaging results for the correct patient are displayed in the operating room

Sign out

Before the patient leaves the operating room:
- Nurse reviews items aloud with the team
  - Name of the procedure as recorded
  - That the needle, sponge, and instrument counts are complete (or not applicable)
  - That the specimen (if any) is correctly labeled, including with the patient's name
  - Whether there are any issues with equipment to be addressed
- The surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery.[35] For the complete checklist, see the Supplementary Appendix.

the authors noted that omissions in some checklist steps were frequent and they recommended ongoing educational efforts and gathering of data to assure compliance.

The simple act of introducing the WHO checklist does not guarantee that outcomes will improve. An article that compared outcomes before and after introduction of the WHO checklist in hospitals within a single province in Canada was by Urbach and coauthors[52] in the *New England Journal of Medicine,* 2014. Outcomes data were analyzed during three-month intervals before and after introduction of the checklists. Data from more than 109,000 procedures before introduction and 106,000 procedures after introduction were analyzed. The authors found that there was no significant reduction in risk of death or complications following introduction of the checklists. In letters to the editor of the journal that followed publication of this article, important points were made. First, a letter from an auditor who had reviewed checklist use in 10 operating rooms documented wide variability in compliance with checklist components. In a second letter, it was emphasized that the risk of deaths and complications in the report by Urbach was very low,

suggesting that most of the procedures were very low risk and that, more than likely, simply implementing the checklist would not have improved outcomes.

A cluster randomized trial that evaluated use of the WHO checklist was by Haugen and coauthors[53] in *Annals of Surgery,* 2015. This article is included as a full-text reprint accompanying some formats of *SRGS*. The authors reported the outcomes, including complications, lengths of stay, and mortality, in groups that were randomized to either use or not use the checklist. Control procedures included 2,212 operations from several surgical specialties. The checklist group consisted of 2,263 procedures. Complication rates were significantly lower in the checklist group and length of stay was reduced by almost one day. Reduction in risk of mortality was not statistically significant. Of interest was that beneficial effects on outcomes were associated with the degree of compliance with use of the checklist. The authors directly observed actions of surgical teams and confirmed that teams using the checklist completely and faithfully had the largest reductions in mortality and complication risks.

In an editorial that accompanied this article, Haynes and coauthors[54] emphasized the facts that several observational studies have confirmed benefits in terms of improved outcomes after introduction of the WHO checklist. They noted that the current study had analyzed outcomes in patients who were having high-risk procedures performed, where expected risk of deaths and complications were significant. The authors agreed that efforts need to continue to assure complete and consistent compliance with the WHO checklist so that full benefits will be realized.

Another article that confirmed the association of the level of checklist compliance and outcomes was by Mayer and coauthors[55] in *Annals of Surgery,* 2016. The authors analyzed outcomes data on 6,714 patients admitted to five hospitals. The data analysis found that completion of one component of the checklist occurred in 97% of cases, but full completion occurred in only 62% of cases. Mortality was not significantly different in cases where full checklist completion occurred, compared with cases where partial completion occurred. However, cases in which full completion occurred were associated with a statistically significant reduction in risk of complications.

The use of checklists as a means of dealing with crisis situations in the operating room was the focus of an article by Arriaga and coauthors[56] in the *New England Journal of Medicine,* 2013. The authors conducted simulations of operating room crisis situations, such as cardiac arrest or massive hemorrhage, with operating room teams from three hospitals. Each team was randomly assigned to manage the crisis with a checklist or without. Analysis of the observational data showed that process of care steps were missed in 6% of crises managed with checklists compared to 23% of those managed without checklists. The authors concluded that checklists have the potential to improve outcomes in managing operating room crisis situations.

Improvements in health care safety are known to result from increased emphasis on education, training, and engagement of all caregivers. Teamwork training has the potential to improve health care outcomes. Crew resource management training has been a successful means of improving safety in aviation and in complex environments, such as nuclear power plants. In the *Joint Commission Journal on Quality and Patient Safety,* 2007, Dunn and coauthors[57]presented data on the changes that were observed when crew resource management training was introduced in the Veterans Administration (VA) health systems. The authors noted that communication failures were found to contribute to adverse safety events in more than 75% of the 7,000 root cause analyses conducted in the health system. The team-training regimen included a one-day educational session conducted by trained peer professionals, pre- and post-intervention attitude questionnaires, and follow-up interviews. Examples of changes that were implemented include briefings and debriefings before and after operative procedures and adoption of rules of conduct for staff behavior standards. Staff behavior standards stressed respect for all team members, shared responsibility, keeping an open mind, being on time, and constructive listening. The authors noted that the principles of crew resource management focus on safety, efficiency, and morale in the conduct of crew procedures. In the health care setting, training of medical teams emphasized preparation and planning, administration of training, and follow-up educational efforts and procedures to gather data on important outcomes. The

conclusion reached was that introducing medical versions of crew resource management training was both feasible and potentially effective.

An article that evaluated outcomes of association use of the VA health system medical team training program was by Neily and coauthors[58] in *JAMA,* 2010. The study evaluated surgical outcomes in the VA health systems after introduction of operating room briefings and debriefings. Data from nearly 200,000 procedures performed in 108 hospitals were analyzed. Results from 74 facilities that had implemented the training program were compared with results from 34 hospitals that had not yet implemented the program. The study interval was two years. The data analysis showed an 18% reduction in mortality risk in facilities that used the program, compared to a 7% reduction over the same time interval in facilities that had not implemented the program. The authors concluded that introducing medical team training resulted in improved outcomes.

Baker and coauthors[59]also focused on the value of teamwork in complex environments in *Health Services Research,* 2006. The authors defined a "team" as a group of two of more individuals who have specific roles, perform individual tasks, are adaptable, and share a common goal. Key features of successful teams include essential knowledge, skills, and attitudes. Team members effectively monitor their own and teammates performance, gain understanding of all team members' responsibilities, and have a positive disposition regarding working with the team. Data cited by the authors indicate that successful teams are those that emphasize mutual performance monitoring, adaptability, shared mental models, mutual trust, and willingness to take others' behaviors into account during group interactions. Team leadership is an important component of success. Leadership stresses a common purpose with clear, but not overly rigid, roles for team members. Leaders conduct effective meetings and foster a working environment where team members believe that the team leader and their colleagues care about them. Research described in the article confirmed that adoption of such a team structure results in improved team attitudes and smoother team functions. Documenting a reduction in events such as nuclear power plant failures and airplane crashes as a result of teamwork has been difficult because of the rarity of these events, but surrogate measures, such as assessments of team function and attitudes, have confirmed the effectiveness of team training. Several descriptions of team training models and research studies are included in the article.

A systematic review of literature to determine the effectiveness of teamwork, communication, and an emphasis on safety when creating an improved surgical culture was presented by Sacks and coauthors[60] in *BMJ-Quality and Safety,* 2015. The authors reviewed 47 studies to determine effects of improvements in teamwork, communication, and safety climate in surgical settings. All of the included studies documented improvement in at least one of the three domains, and two studies showed that improvements in at least one of the three domains was associated with improved surgical outcomes. The authors concluded that focused efforts by health care institutions to improve communication, teamwork, and the safety culture have potential to improve health care outcomes.

Prevention of Surgical Never Events

The term "surgical never events" refers to retained items after completion of the procedure, wrong-patient/wrong-side/wrong-site procedures, and surgical fires. A review article that described the magnitude of this problem area and the results of efforts to minimize never events was by Hempel and coauthors[61] in *JAMA-Surgery,* 2015. The authors conducted a systematic review of available literature and identified 138 studies that were acceptable for inclusion. The analysis showed that the reported rates of wrong-site surgery and retained surgical items varied according to procedure type. Average frequencies were 1 per 100,000 procedures for wrong-site surgery and 1 per 10,000 procedures for retained surgical items. Data were insufficient to determine a rate for surgical fires. Although evidence was limited, the authors found that there was support for the use of the Universal Protocol (see later discussion), education, and team training to prevent wrong-site surgery. Evidence was limited that supported the use of matrix-coded sponge counting systems for reducing rates of retained items. The authors noted that the Universal Protocol was introduced in 2004 as part of an effort by the Joint Commission on Accreditation of

Healthcare Organizations to reduce wrong-site surgery. The protocol consists of three parts: (1) preoperative verification of patient identity; (2) marking of the operative site, and; (3) a preoperative time-out for operative team briefing and confirmation of patient identity and surgical site verification. The authors stated that research that could verify the effectiveness of this protocol and other efforts to reduce the risk of retained items and surgical fires has been scarce. Their systematic review suggested that inadequate communication was a frequent contributing cause of both wrong-site surgery and retained surgical items. No dependable data on the risk of surgical fires or effective efforts to minimize fire risk were found. The authors stressed the fact that assessments of interventions for rare events is challenging. They also acknowledged that most quality improvement initiatives in surgery are designed to affect multiple processes, and that this limits the ability to ascribe an improved outcome to a specific intervention. Hempel and coauthors concluded that available data supports the use of interventions to improve communication, including using the Universal Protocol to reduce risk of wrong-site surgery and retained surgical items.

Mallett and coauthors[62]presented a method for analyzing causes and developing remediation strategies for never events in the *American Journal of Medical Quality,* 2012. In their article, the authors described the response to the occurrence of eight wrong-site surgery events in a single hospital over a two-year interval. They reported that the hospital conducted a root cause analysis of each event and the investigators then performed a common cause analysis using each of the root cause analysis records. The common cause analysis identified was insufficient detail in the consent forms—laterality and procedure site information were missing for several consent forms. The authors also discovered problems in workflow responsibilities and in the transfer of information regarding the patient; the need to compare information in all source documents was often not recognized. An additional observation was that the "time out" for team briefing and information confirmation as required by the Universal Protocol was subject to variable compliance. Based on these findings, the authors developed a Universal Protocol checklist and established educational efforts to make certain that teams were appropriately trained to comply with the Universal Protocol. A system of external auditors was established to document compliance and gather data regarding efficiency and compliance with the established processes. The authors concluded that these efforts led to improvements in compliance, communication, and process completion rates.

Stawicki and coauthors[63] reported data on the frequency and risk factors for retained surgical items in the *Journal of the American College of Surgeons,* 2013. Determining accurate frequencies and identifying risk factors for rare events such as retained surgical item events can be challenging, and in an attempt to adjust for this, the authors conducted a multi-center case match study during the interval of 2003 to 2009. They were able to match 59 retained surgical item events with 118 matched controls. The analysis showed that retained surgical items events occurred despite the use of confirmatory x-rays and/or radiofrequency tagging of sponges. Risk factors for retained item events included increased patient body mass index, procedure duration, and unexpected intraoperative events. Any incorrect sponge count during the procedure was associated with increased risk. Of interest was that participation by trainees in the procedure significantly lowered the risk of a retained item event. The authors found that procedures continued to completion, despite incorrect sponge counts, in 10 of 59 cases; incorrect sponge counts are frequently "false alarms," according to the authors, and they hypothesized that a degree of "alarm fatigue" may contribute to the decision to complete the procedure despite an incorrect count. This departure from safe procedural process is a target for improvement. Education for improved communication and the implementation of a "hard stop" policy and protocol for responding to incorrect counts can contribute to a solution.

The same group of investigators presented an article on the natural history of retained surgical items and how this history can contribute to effective solutions to this problem.[64] The article reported a post-hoc analysis of the data from the previously reported multi-center study. The data were examined to determine the location of the retained item, the interval from occurrence to discovery, presenting signs and symptoms, procedure and incision characteristics, pathology reports, and patterns of safety omissions or variances (SOV). Common SOV included lack of verification in medical record, retained item missed on x-ray, counts not performed or documented, incorrect

protocol execution, protocol disregarded, lack of safety knowledge, and inadequate team communication. The data analysis showed that among 71 retained item events there were four deaths—with the retained item contributing to one of these deaths. Nearly two-thirds of the retained event procedures occurred on the day of admission to the hospital. Twelve of the retained items had been placed at a referring hospital. Most of the retained items were in the abdomen. Among symptomatic patients, pain, abscess/fluid collection, and palpable mass were the most common findings. Detailed review disclosed that team/system errors predominated, and isolated human error was confirmed in less than 10% of cases. The authors found that patterns of retained item location were related to the type of procedure performed. For example, most retained items after caesarian section were located in the subcutaneous space. Given the frequency of team/system SOV involved in retained item events, specific team training may be an important means of reducing the risk of these events.

Patient Safety & Care Handovers

Multiple changes in the way that care is delivered in academic medical centers have contributed to the increased number of transfers of patient care responsibility from one caregiver or caregiver team to another. These changes include the increased use of multidisciplinary teams to deliver care in the perioperative period and resident duty hours limitations. Data are available that support the conclusion that errors made during handovers contribute to patient safety events that may result in patient harm. An article that presented data on the effectiveness of interventions to improve the quality of handovers was by Pucher and coauthors[65] in *Surgery,* 2015. The authors stated that handovers are frequently unstructured, unstandardized, and prone to errors in information transfer. Such errors frequently lead to patient care errors that may cause patient harm. The Joint Commission for Accreditation of Health Care Organizations (JCAHCO) has produced guidelines for developing interventions to improve handovers. The guidelines have five domains: Standardization of critical content; Hardwiring within the hospital system through use of checklists; Allowance of opportunities for team members to ask questions; Reinforcement of quality and measurement through incorporation into clinical governance structures and ongoing audits of outcomes and formal educational programs for training in development and use of effective turnover techniques. Pucher and coauthors described their systematic review of available literature in order to determine the number and the effectiveness of handover interventions and the degree to which these interventions comply with JCAHCO guidelines. Nineteen studies met the review requirements. Most of the interventions relied on paper or computerized checklists or standard operating protocols. Most of the reviewed studies documented improvements of the handover process, but descriptions of development methods, staff training, and follow-up outcomes data were of poor quality; only one of the 19 studies complied with all five domains of the JCAHCO guidelines. The authors acknowledged that research into design and implementation of effective handover techniques is relatively new, and nearly three-quarters of all peer-reviewed publications on these topics have appeared in the past five years. The authors concluded that checklist-based efforts to improve the quality of handovers may be effective in reducing the risk of patient harm, but that the risk of bias in the available studies is high. Also, the failure to comply with the five domains of the JCAHCO guidelines is concerning. The most common domains that were neglected were reinforcement and education, which are felt to be the most critical domains for producing change that is durable and of high quality. The authors emphasized the importance of staff training and accountability. One potentially useful method for achieving this might be the use of simulation. The authors recommended additional high-quality research to help guide the development of improved handover methods.

Effectiveness of Patient Safety Interventions

In this section of the overview, we will review articles that assess the effectiveness of patient safety interventions.

The first article reviewed was by Baines and coauthors[66] in *BMJ-Quality and Safety,* 2015. The authors conducted retrospective medical record reviews at 21 hospitals in three time intervals (2004,2008, and 2011 to 2012). Nearly 16,000 admissions were reviewed. The

intent of the review was to determine if there had been changes in the rates of adverse events and preventable adverse events after two national efforts to improve patient safety had been introduced in 2003 and 2008, respectively. The analysis showed that the overall frequency of adverse events had not changed over the three time intervals studied. Preventable adverse events had decreased (30% after multiple statistical adjustments for confounders), but this decrease was not statistically significant. Two areas where the reduction of preventable events was most apparent were surgical processes and care for elderly patients. The authors emphasized the facts that multiple changes in processes and approaches to patient care had occurred simultaneously with the introduction of the national patient safety initiatives, and that these changes could have influenced the search for the effects of patient safety programs. Other data cited by the authors indicated that hospital compliance with the patient safety programs reached its maximum point in 2011; this could have caused a reduction in observed preventable events. The authors concluded that identifying impact of patient safety initiatives is challenging, but the data suggest that there is a possible beneficial effect from national efforts to improve patient safety.

A description of one national effort to improve the quality and safety of surgical care was presented in an article by Ko and cauthors[67] in the *Joint Commission Journal on Quality and Patient Safety,* 2015. The authors described the evolution and changes in quality outcomes associated with the introduction and subsequent growth of the ACS NSQIP program. The program started in 2004 and was adapted from a similar program that had been used in VA health systems. By 2015, the NSQIP program had been introduced in 600 hospitals. The program provided hospital and surgeon-specific risk adjusted outcomes data. The database contained millions of patient records and used more than 100 risk adjustment models. The authors cited data from several research studies that showed an association between participation in NSQIP and improved patient outcomes in participating hospitals. A by-product of the program has been the development of regional quality improvement collaboratives that have demonstrated improved patient outcomes after they began to implement quality improvement program changes based on outcomes data from the NSQIP database.

The authors listed several important lessons learned by hospitals using NSQIP to assist with quality improvement initiatives. These included the search for contributing factors that influence the quality problem that requires improvement, recognition that local factors will influence the ability to use clinical guidelines and quality improvement tools, and the importance of excellent communication. The final lesson learned was the critical importance of data gathering and feedback of information about quality efforts. The authors concluded that NSQIP has the potential to assist hospitals and surgeons as they search for ways to achieve high-quality care.

Osborne and coauthors[68] reported information on a study designed to determine the association of participation in a quality reporting program with surgical outcomes and costs of care in *JAMA,* 2015. The authors used national Medicare data to compare outcomes of surgical care in hospitals that participated in the ACS NSQIP program with outcomes in nonparticipating hospitals. Data from nearly 1.3 million patients who underwent general and vascular surgery procedures in 263 NSQIP-participating hospitals and 526 nonparticipating hospitals were analyzed. Thirty-day mortality and the frequencies of complications such as myocardial infarction, renal failure, and pneumonia were points of comparison. Mean Medicare payments were compared at 1,2, and 3 years after beginning NSQIP participation and compared with data from nonparticipating hospitals. The analysis showed that there was no statistically significant difference in any of the comparison variables at 1,2, and 3 years after beginning NSQIP participation. There were also no differences in mean Medicare payments observed. The authors offered explanations for the observation that NSQIP hospitals did not show improvements compared to non-NSQIP hospitals: First, hospitals had not had time to conduct specific quality improvement efforts, or, they had introduced some of these efforts, but improvement did not occur; Second, participation in pay-for-performance programs and value-based purchasing efforts could have led to improved outcomes in nonparticipating hospitals that would obscure a difference brought about by NSQIP participation.

The final article reviewed in this section presented data on the results of implementing quality improvement initiatives that have been successful in industrial settings

in an effort to improve operating room efficiency in a high-volume tertiary referral hospital. Industrial quality improvement efforts such as LEAN (an effort to eliminate waste in manufacturing processes) and Six Sigma (a quality improvement effort designed to eliminate errors in a process) are potentially useful ways to improve operating room efficiency.[69] The intent of the interventions was to eliminate operating room over or underuse, streamline the preoperative process to reduce redundant efforts in patient evaluation and testing, optimize efficiency of operating room turnovers, eliminate collection and documentation of redundant patient information, and improve employee engagement. The authors constructed detailed process maps for each of the chosen functions. This effort resulted in several important findings: accurate information on operating room capacity was not accurately communicated to surgeons who were scheduling procedures, and preoperative evaluations were being conducted by multiple groups without a standardized approach—this factor was impacting the operating room's ability to achieve on-time starts. Improvements in operating room turnover were achieved by:

1. Preparing for subsequent cases during the preceding case.
2. Making a specific effort to reduce collection of redundant patient information.
3. Organizing a communication council to improve employee engagement.

After these efforts were implemented, data collection showed significant improvements in on-time starts; reductions in room turnover time were also observed. The implementation of these efforts was also associated with improvements on operating room profit margin as well as employee satisfaction levels. The authors concluded that a comprehensive quality improvement effort using LEAN and Six Sigma techniques was feasible and effective in operating room areas.

The Business of Medicine

The American health care system is and will continue to face significant challenges. A major consideration is the need for ongoing efforts designed to control health care costs. Additional issues include strategies for creating successful and sustainable health care institutions. Health systems leaders have turned to strategies such as employing physicians, creating mergers and consolidations, and organizing accountable care organizations to help ensure continued survival of their enterprises. In this section of the overview, articles will be reviewed that deal with topics relevant to the business aspects of health care.

The American Health Care System

A major issue currently facing today's health care system is choosing the best way to achieve success and sustainability in an era where the system's cost is believed to be intolerable. Fineberg[70] provided insight into this topic in the *New England Journal of Medicine,* 2012. The author asserted that health care in America is not as successful or as sustainable as it should be. The Affordable Care Act (ACA) has provided funding for cost containment and improved population health. A critical concern is the need to reduce wasteful health care practices that drive up costs, while also pursuing improvements in disease prevention and management that could lead to improved population health. The author emphasized that population health improvement is the desired outcome for any improved health system. To achieve reductions in cost and improvements, health care needs to be available to all Americans and patient-centered; this will lead to the optimum health status of each individual. Furthermore, the system needs to be fair to health care providers and to businesses that support the delivery of care. Finally, the health system of the future must be affordable and must recognize that government and businesses that provide financial support for the health system rely on citizens to be consumers and taxpayers so that the health system will survive.

Fineberg cited data that support the conclusion that the American health system has delivered benefits to the citizens of this country. By 2009, life expectancy increased to more than 78 years. Despite this fact, several countries have longer life expectancies than the United States. Health system performance in the United States placed last in the recent health system assessment conducted by the Commonwealth Fund. Concerns over the cost of the American health system are linked to concerns about national debt. The two main drivers of debt in this country are spending for defense and for entitlement programs. Currently, Medicare and Medicaid costs exceed the total costs for Social Security. The most acceptable way to contain health care costs is through performance improvement that provides more value for the dollar spent. The potential cost savings from increased efficiencies in health care are significant. Data cited showed that reductions in waste could save up to 765 billion dollars annually—these costs do not improve the health of Americans and are mainly comprised of unnecessary services, excess administrative costs, and services that are inefficiently delivered.

Fineberg endorsed increasing efforts to enhance quality and safety of health care. Payers should be encouraged to use financial incentives to improve care and be allowed to impose penalties for wasteful or unnecessary services. The success of many performance improvement programs in health care institutions, such as the program to reduce bloodstream infections, has provided evidence that institutional initiatives to reduce costs can work. The author also supported improved methods of care for patients with high-cost medical problems that would focus on reducing the need for in-hospital care. The third recommendation was for increased use of patient-centered approaches that take note of patient preferences, especially for the elderly and for patients with late-stage illnesses. Also noteworthy was the need to improve patient flow through the health care system via efforts to reduce crowding and streamline patient flow, especially those patients in need of complex specialty care. Another recommendation was for all health care providers to be incentivized to gather data on performance and to participate in performance improvement projects. Lastly, Fineberg encouraged health care providers to embrace accountability over autonomy and support team-based care and ongoing education, and concluded by reminding us that no one thing will solve the current health system's problems—many approaches will need to be tried.

Another article that provided perspective on approaches to controlling health care spending was by Emanuel and coauthors[71] in the *New England Journal of Medicine,* 2015. This article is supplied as a full-text reprint accompanying some formats of *SRGS*. The author cited data showing the significant negative effects of uncontrolled health care spending on the national economy. If current trends continue, health care spending could restrict investments in education and infrastructure and reduce wages for the middle class. The author recommended the adoption of global health care spending targets at the state level. Negotiated rates between providers and payers would be required to adhere to these global targets. An associated aim would be to link increases in health care spending to wage increases. An independent council of providers, payers, consumers, and economists could be formed in each state to set and enforce this spending target. Government funding for research, training, and uncompensated care should be separated from Medicare and be linked to global spending targets.

Emanuel and colleagues recommended bundled payments that would be divided among all providers of a service—as opposed to the episode-of-care system that is currently used. Adding competitive bidding for devices and medical equipment could improve competition and lower costs. Providing incentives to patients to direct them to high-value providers might also lead to reduced costs.

Additional cost control avenues include requiring price transparency for all services, instituting efforts to reduce administrative costs, making better use of nonphysician providers, and reducing the costs of defensive medicine.

The ACA became law in 2010. The primary goals of the law were to provide improved availability of health insurance, improve health care quality, and reduce costs. Blumenthal and coauthors[72] provided an assessment of the law after five years in the *New England Journal of Medicine,* 2015. The authors indicated that the law will be judged on progress, or lack thereof, in three areas: access to health care, the cost of health care, and the quality of health care provided. They argued that the clearest success

of the law has been in increasing the proportion of citizens with access to health insurance. This gain has occurred in groups that have traditionally had high proportions of uninsured individuals (young adults, Hispanic citizens, black citizens, and citizens with low incomes). Expansion of Medicaid enrollment has occurred even in states that chose not to take advantage of the Medicaid expansion aspect of the law, and this has also helped reduce the proportion of uninsured citizens. Finally, nearly three million young adults 26 and under joined their parents' insurance plans.

The law provided for several changes in payment plans and offered opportunities to improve primary care through research into innovative payment and organization. These changes are moving forward in concert with efforts supported by the law to increase the attractiveness of primary care as a health care career. One unfulfilled promise has been establishing a national commission on the health care workforce. The authors concluded that the law has improved access, but that it is too soon to conclude that there have been meaningful improvements in health care quality and better control of health care costs.

Strategic Imperatives in Health Care

Important changes that are forcing health care institutions and health systems to reexamine the way they conduct business include the fact that reimbursement is decreasing and payers are increasing demands for price transparency and increased quality of care. Porter and Lee[73]provided insight into some of these issues in an opinion piece in the *New England Journal of Medicine,* 2015. Recognizing the changes that are occurring in the health care system led the authors to recommend that health care institutions and systems acknowledge the importance of examining organizational strategies and adjusting these to meet the future goals of the organizations. The authors recommended that health care organizations answer six questions that would help to begin examining strategic initiatives, including:

1. What is the fundamental goal of the organization? To succeed in the future state of health care, emphasis should be placed on improving outcomes and reducing costs, rather than on maintaining a profit margin.
2. How do you identify the business you are in and how you will differentiate yourself? No effective organization should try to meet the needs of every customer. Emphasis needs to be placed on outcomes and cost reductions. Organizations should try to create synergies by providing services at the most cost-effective location and consolidating based on the medical condition being treated and the best location for that treatment to occur.
3. What is the organization's geographic scope? Service location and density should be decided based on appropriate caseload volumes that will permit the creation of value.

One avenue for organizing practice locations and geographic scope is through the development of integrated practice units—multidisciplinary teams with expertise, skill, and range, who can use facilities to achieve good outcomes for a chosen condition. Partnerships and affiliations can be a valuable means of achieving the necessary caseload volumes, and these units can also embrace and maximize the benefits of bundled payment plans.

Tsai and coauthors[74] evaluated the relationship of management practices in health care organizations to health care outcomes in *Health Affairs,* 2015. The authors used data from the World Management Survey that includes data on interview findings gathered from 2,000 hospitals in the United States and England. The survey provides scores based on interviews with managers, ranging from 1 to 5, with 5 being highest. Scores were based on responses to 20 management questions and were adjusted based on the management role of the interviewee. Hospital board behaviors were assessed, focusing on the board's emphasis on quality and the use of quality metrics. The analysis showed that higher management scores were associated with the delivery of higher quality care and improved health care outcomes. Similarly, boards that emphasized quality and regularly examined quality metrics were most often those that led high-quality health care institutions.

An important development in health care that is impacting the business of health care institutions is the rise of retail clinics. Two articles reviewed at this time examined the system-wide effects of these new approaches to the provision of health care.

The first article was by Iglehart[75] in the *New England Journal of Medicine,* 2015. The author identified several characteristics of retail clinics that are unsettling to traditional health care delivery entities, especially in family medicine and pediatrics practices. Retail clinics offer basic primary care, extended hours, ability to obtain walk-in appointments, and lower costs than traditional doctors' offices and emergency departments. Urgent care centers are costlier than retail clinics but offer more complex services. Large companies such as CVS, Walgreens, Kroger, Target, and Rite Aid now operate more than 1,700 clinics. Recently, Walmart announced its intent to open retail clinics as well. Although the quality of care offered by retail clinics has been questioned, available data cited by the author have not confirmed delivery of lower quality care by retail clinics. Recognizing that many patients do not have a primary care physician, some medical professional societies have worked to establish a complementary relationship between retail clinics and traditional health care delivery systems. One fact that has emerged from research on retail clinics is that these facilities are commonly located in high-income areas. This fact raises the question of how these facilities might serve lower-income portions of the population. Data cited by the author support the conclusion that the growth of retail clinics has not "transformed" health care delivery. ACA restrictions on professional activities of nurse practitioners have increased costs of running retail clinics. It is possible that removing such restrictions will ease some of the financial problems these clinics have.

Dalen[76] provided more perspective on the development and growth of retail clinics in the *American Journal of Medicine*, 2016. The author noted that the first retail clinic was opened in Minneapolis, Minnesota in 2000. By 2015, there were 1,900 retail clinics—3,000 clinics are predicted to be operational by the end of 2016. According to data cited by the author, the main reason patients visit retail clinics is convenience. Additional data confirmed that one-third of the U.S. population lives within a 10-minute drive of a retail clinic. While criticisms of retail clinics have been based on quality of care, research cited by the author confirmed that there are no differences in quality of care compared with traditional physician care. As suggested previously, retail clinics have recognized that most patients using their services do not have a primary care physician, and data cited by the author suggest that there are efforts by retail clinics to provide access to primary care providers for patients; these efforts have been assisted by the integration of electronic health records. Of interest is the recent move of retail clinics to establish relationships with health systems, such as the Cleveland Clinic, the Henry Ford system, and the Kaiser Health System. These relationships have been associated with an increase in the types of services offered by the clinics and the introduction of chronic disease care into the scope of practice. These relationships may indicate a move from fragmentation of health care by retail clinics to a more integrated system that includes these retail facilities.

Mergers & Consolidation

Recent history of the American health system has confirmed an increasing number of mergers and consolidations involving health care institutions and systems. This has raised concerns that larger providers will demand higher payments from insurers and contribute to increasing health care costs. Tsai and Jha[77] provided information on the rate and effects of health care mergers in *JAMA,* 2014. The authors provided the arguments in favor of health care mergers: (1) higher-volume institutions are created and this should be associated with better outcomes; (2) mergers will result in an increase in "integrated" care; (3) mergers will produce organizations able to make investments in initiatives to improve care, such as electronic medical records. The authors stated that a more persuasive argument could be made if data showed improved health outcomes associated with a merger. The authors also argued that improved outcomes do not always equal higher volumes, because the volume-outcome relationship varies widely across conditions and outcomes. The volume-outcome relationship is most dependably observed in certain high-complexity surgical procedures, such as esophagectomy. Additional data cited by the authors support the conclusion that the volume-outcome relationship may be a surrogate for a set of high-quality care processes.

Tsai and Jha emphasized that high-quality health care is associated with high-quality data. Health information exchanges may be resources for sharing health care data, which can lead to improved outcomes. Larger organizations created by mergers may be less interested in sharing data and this could impede improvements in health care. The authors concluded that there is no data available to support the assertion that larger institutions are better able to invest in systems that can improve quality, and that the three typical reasons given to support mergers and consolidations are not supported by strong evidence.

An article that provided perspective on the characteristics of a "good" merger was by Dafny and Lee[78] in the *New England Journal of Medicine,* 2015. The authors asserted that a good merger is one that increases the value of health care by reducing costs, improving outcomes, or both. Unfortunately, the most common result of health care mergers is increased costs, especially when the merged institutions are in close proximity. The authors suggested that outcomes of mergers could be improved if stakeholders clearly defined goals and metrics for evaluating success before mergers are consummated. Such definitions will help stakeholders and regulators assess the merits of the proposal and will also create public commitments that can facilitate plans to reach the defined goals after the merger occurs. The authors recommended that leaders of proposed health care mergers use the same rigorous methods to evaluate potential merger efficiencies that other businesses do. Articulating the potential benefits and risk and confirming that accountability for achievement is in place will most often lead to a "good" merger.

Three articles described a failed health care merger and illustrated the need to carefully evaluate the economic and cultural factors that will determine success or failure of the merger; these articles will be reviewed at this time.

The first article reviewed was by Kastor[79] in *Academic Medicine,* 2010. This article is the first of a two-part analysis of the failed merger of the Mount Sinai and New York University (NYU) medical schools and hospitals. The author noted that the main reason this merger was considered in the first place was economic—the hope was that economies of scale would reduce direct costs and permit an economically sound response to an environment where reimbursement was diminishing. The author added that mergers were thought to be a potential remedy for the effects of managed care on reimbursements. The initial merger plan was to combine the two medical schools, along with their hospitals. This proposal raised concerns, especially in the NYU faculty, who viewed their medical school as superior to the Mount Sinai school and feared that merging the schools into a separate corporate entity would threaten tenure rights. The Mount Sinai faculty believed their school was ascending while NYU was receding, and they emphasized the fact that Mount Sinai had significantly more NIH research funding than NYU. The Mount Sinai faculty also believed that the financial position of Mount Sinai was stronger than that of NYU. Combined with all of these sentiments was the fact that a very strong voice at the NYU medical school, the dean at the time, declined to take a position on the merger. In 1997, a formal announcement was made that the merger of the hospitals and medical schools had failed and that a merger of the hospitals was being pursued.

The second article, also by Kastor,[80] described the outcome of the merger of the two university hospitals. Economic concerns surfaced almost immediately: the NYU hospital had little debt, while Mount Sinai had recently incurred a large debt to build a new clinical building. Leadership of the NYU trustees felt that merging the hospitals was a large gamble. Another concern at NYU was that hospital revenue was used to support academic programs at the medical school—there was serious worry that creating a new corporation would lead to the discontinuation of this support. In addition, there was a recognized need for capital improvements to the NYU hospital that many feared the new corporation would not be interested in investing in. NYU faculty concerns led to a lawsuit filed by the faculty council to prevent the separation of the NYU medical school from the hospital. The suit was dismissed and the NYU trustees supported merging the Mount Sinai Medical School with NYU. Kastor concluded that the combination of financial fears and faculty opposition doomed the second merger, which dissolved in 2008 with high costs to both institutions.

Grossman and Berne[81] offered a final opinion on the fate of the two mergers in *Academic Medicine,* 2009. The authors confirmed that serious cultural and financial issues affected the outcome of the merger: a proposed $1 billion loan that was to be provided to the new corporation after the hospitals merged did not materialize, and

this placed additional financial strain on the relationship. In addition, the anticipated economies of scale that had been touted as a financial benefit of the merger were not realized. Cultural issues were not addressed promptly. Time was not taken to win over stakeholders, and this created a poisonous atmosphere that damaged the merger. The authors concluded that the main lesson learned was that larger may not be better—unless the combined institutions have the operational and leadership capacity to manage the merged entity. Also critical is the willingness to invest time and effort in creating the trust that is needed to make the merging of two cultures successful. In the Mount Sinai-NYU merger, the main strengths of each institution were undermined by the merger. The recognition of this by the faculty of both institutions led to disaffection with the merger process.

The Electronic Health Record

There is signification disaffection for the electronic health record by health care professionals. The most commonly cited problems are that available health records were created to support billing activities, not patient care, and that the needs and concerns of health care providers have been largely ignored by the manufacturers of electronic health record systems.

Rosenbaum[82]examined the problems associated with the electronic health record in the *New England Journal of Medicine,* 2015. The author summarized the topics addressed in Robert Wachter's book *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age.* In one instance, the defaults built into the electronic health record contributed to the delivery of a 39-fold greater dose of a medication to a patient. Also contributing to this error was "alarm fatigue," in that the caregiver responsible for ordering the overdose had been exposed to a large number of alerts and chose to ignore an important one. Wachter concluded that the effect of the electronic health record on the psychology of caregivers was responsible for much of the angst, and stories of harm have led to an enormous amount of criticism for the health record. According to data cited by the author, doctors who express concern about limitations of the electronic health record are often labeled as technophobic, resistant, and uncooperative. Additional data showed that no other industry had been subject to a universal mandate to adopt new technology before the effects of that technology were fully understood. In one example, a physician was forced to abandon an effective patient education effort because a government mandate required the use of educational materials suggested by the electronic health record.

The author concluded that the major obstacle to successful adoption of the electronic health record is the failure to permit health care professionals to become part of the development process. Until this obstacle is overcome, the focus will be on problems with the electronic health record, and not its potential to assist in improving the quality of health care.

New Payment Models in Health Care

Recognition that the continued rise in health care costs is a dire threat to the economy of the United States has stimulated consideration of new payment models for both government-funded and private health insurance. The emphasis on population health that was included in the ACA has prompted payers to focus on population health as a desirable metric to determine reimbursement.

In their article in *New England Journal of Medicine,* 2009, Hartzband and Groopman[83] asserted that changes in the ways that medical practice is viewed are, in part, a reaction to the 2007–2008 financial crisis; this article is included as a full-text reprint accompanying some formats of *SRGS*. Currently, all aspects of medical practice are viewed through a lens that emphasizes finances. A value is placed on every aspect of a physician's workday and financial metrics are reported to the physician in ever-increasing volumes. Using these metrics, payers make assessments of the cost-effectiveness of a physician's work. The authors cited data from research in the field of behavioral economics that provided evidence that increasing financial scrutiny of an activity may actually lead to reduced productivity and increased cost. The mere suggestion of economic scrutiny promotes behaviors marked by selfishness and lack of collegiality. The authors emphasized the fact that medical practice has communal and marketplace elements. Physicians are paid for providing services, but the communal elements emerge when help is needed and physicians supply that help without regard

for payment. The current emphasis on economics and marketplace elements threaten to crowd out communal elements. Increased emphasis on economic issues in medical practice could lead to physicians adopting a practice approach whose main goal is achieving the mandated bottom line. This could potentially cause reductions in the laudable aspects of practice, including pride of profession, sense of duty, altruism, and collegiality. One change in medical practice that has already been created by these economic forces is the rise of concierge medical practice. Concierge physicians frequently cite the benefits of this practice pattern, including increased opportunity for personal and social interactions with patients and a decreased emphasis on economic factors. While this change may improve the lives of concierge physicians and the patients they serve, the grim truth is that the overwhelming majority of American citizens cannot afford to enter concierge practice arrangements.

An article that focused on one aspect of changed methods of payments to physicians was by Mulcahy and coauthors[84] in the *New England Journal of Medicine,* 2015. The authors stated that concern over the cost of fee-for-service approaches to physician payment has led to the use of bundled payments for groups of services. According to data cited by the authors, these bundled payments have been suggested to lead to reduced costs without detrimental effects on health care quality. Recently, however, Medicare decided to discontinue bundled payments for perioperative services in a move that surprised many health care economists. The traditional method of payment had included a global payment for all services supplied within a defined period following the operation. Results of assessments performed by Medicare showed, however, that the number of postoperative visits that were actually occurring were significantly fewer than the amount being paid for. In addition, there was evidence that members of multidisciplinary teams that were providing perioperative care were billing for their services, resulting in double payments for services because of the global fee approach. Research described in the article disclosed that this action may have significant economic consequences for surgeons. Reducing payment for postoperative visits, many of which require an amount of work similar to the procedure itself, could result in reductions of payments to surgeons exceeding 22%. However, if surgeons began to perform more postoperative visits, the reductions could be smaller. Some investigators believe, according to the authors, that the change in global fee payments will encourage surgeons to make more postoperative visits, particularly on the day of the procedure. Another potentially beneficial consequence could be the development of a plan to monitor the number of postoperative visits and to document services provided by nonsurgeon team members. Having these data could produce a situation where improved reimbursement of all providers could occur with new payment reforms.

Bloche[85]provided information on one aspect of the political response to increasing health care costs in the *New England Journal of Medicine,* 2012. The author noted that the political response to increasing costs of health care has usually focused on eliminating unnecessary services. The common wisdom has been that 30% of health care costs are due to unnecessary services and that eliminating these would save $800 billion. A problem recognized by researchers has been that identifying useless care is only possible in retrospect and there is currently no method for predicting when useless services will be provided. Comparative effectiveness research could provide guidance on ways to eliminate useless care, but such research is expensive and takes years to complete. The authors confirmed that it is becoming increasingly evident that controlling health care costs is going to require reducing some beneficial services. Accountable care organizations may achieve efficiencies and quality, but rewarding these organizations for reducing costs could encourage physicians to avoid tests and services that could benefit patients.

Another approach to controlling costs is the "luxury tax" that is imposed on employer-sponsored health insurance. Unfortunately, employers are likely to pay for this tax by lowering wages, thus shifting the burden to the employee. It has become clear that all of the cost control plans put forward by politicians of both parties will probably reduce beneficial medical services and new pharmacologic agents and devices—the adverse consequences of this on the population's health may be significant. The authors stressed the importance of having politicians acknowledge this consequence and support the development of methodologies to reduce beneficial medical services in a way that has the smallest negative effect on the health of citizens.

The emergence of accountable care organizations (ACO) has changed the focus of medical service providers from treating diseases to improving health. An article that described the time course and effects of these changes was by Asch and Volpp[86] in the *New England Journal of Medicine,* 2012. The authors noted that one factor influencing the change of emphasis from treatment of disease to preservation of health is the recognition that social determinants of health are as powerful an influence as disease. Health care outcome disparities persist even when systems are put in place to provide equivalent health care quality to all segments of a population. This persistence is thought to be due to social factors that influence health, such as poverty, environmental factors, and personal behaviors. As recognition of the importance of population health increases, employers and government agencies will likely shift from paying for treatment of disease to promoting wellness. It is important for the medical profession to recognize the goods and services that the "customers" are seeking and find ways to make improving health the business of medicine.

When adopting the ACO approach to providing health services, an important question arises: can academic medical centers participate in such organizations? Berkowitz and Pahira[87] provided insight into this issue in *Academic Medicine,* 2014. The authors pointed out that the Medicare Shared Savings Program that is part of the ACA has provided support for the development of ACO care models. As of 2014, there were 253 Medicare ACO entities, of which 20% involved academic medical centers. Evidence confirms that the core functions of the academic medical center (including the provision of complex specialty care, primary care activity, generation of new knowledge, and the education of future health care professionals) can occur during and after transitioning to an ACO model; however, in order for a successful transition to occur, several important features of the academic medical center organization have to be in place. The authors cited available ACO readiness tools that focus on several features of academic medical center organization, including structure, leadership, governance, use of information technology and data systems, as well as a set of processes that promote care management and population health.

Berkowitz and Pahira observed that academic medical centers are frequently safety net institutions that provide care for a population with a high burden of chronic disease, substance abuse, mental illness, and poverty. In this system, resident physicians will be responsible for ordering costly tests and treatments—but attending physicians will be responsible for assuring high-quality outcomes. Because of these facts, the academic medical center will have to be ready to convert to a team approach for care delivery that permits all team members to efficiently perform their assigned tasks. Information technology will need to be present and able to inform caregivers of data concerning outcomes and costs. Data will also be useful for developing effective care management processes. The need for academic medical centers to perform clinical and translational research (that often takes years to complete) will need to be recognized, in addition to the need for rapid continuous process improvement that is needed for ACO success. Advanced information technology that can allow ongoing data gathering and analysis will assist in achieving these goals.

Changes in organizational structure will be necessary to facilitate the transition to an ACO model. The authors noted that academic medical centers that are adopting the ACO model have created new leadership positions (such as Chief Transformation Office) to lead these efforts. These are positions of leadership that reside in the ACO as well as within the academic medical center structure. Use of physician leaders is an important component of this effort.

The academic medical center will need to have or acquire a broad primary care network in order to succeed as an ACO. Primary care providers will need to be key leaders in designing the structure and the multidisciplinary teams that will coordinate care in the ACO model. An additional action that may assist in the transition to an ACO model would be for the academic medical center to acquire a managed care plan in order to obtain access to a large population of patients. Relationships with skilled nursing facilities, long-term care facilities, and palliative care providers will assist in ensuring that the entire spectrum of care can be provided.

The authors concluded that academic medical centers have the intellectual strength to succeed as ACO models if attention is paid to all of the domains of function necessary to create and sustain the ACO organization.

Exactly how provision of surgical care is managed in an ACO model is not immediately obvious from the literature that has been produced that is relevant to these models of population health care. Dupree and coauthors[88] presented information on this topic in *Health Affairs,* 2014. The authors reviewed data from the early experiences of 59 Medicare-approved ACO entities using case studies and a survey instrument. The data analysis showed that existing ACO models have invested little time and effort in determining how surgical care will be provided to their patients. The authors recommended that ACO models make surgeons available to primary care teams to offer advice on provision of surgical care and to develop care processes for managing patients with chronic illnesses that often require surgical procedures. For example, targets for developing low-cost interventions could focus on cost-effective preoperative workups. The need to manage chronic diseases that often contribute to poor operative outcomes could benefit from improved teamwork by surgeons and primary care providers. Data provided via the intelligent use of electronic health records could help develop team-based approaches to surgical care within an ACO.

Preparing Doctors for Leadership in Health Care

The first article reviewed in this section of the overview was by Lee[89] in the *Harvard Business Review,* 2010. The topic addressed in the article was the process of incentivizing and preparing doctors to assume leadership roles. The author identified medical progress (development of new drugs and devices) as the main driver of health care costs. The wise application of these new approaches to the care of patients will be necessary to control costs, and leaders with a medical background could be well suited for these roles. Physician leaders can effectively manage information systems that can be designed to evaluate outcomes. Physician leaders must recognize that value in health care means achieving good outcomes with as much cost efficiency as possible. Leading in health care also requires the recognition of the importance of well-functioning teams.

Physician leaders will need to master the art of achieving meaningful and effective change. It is true that there are physicians who believe that there is no "good change" because they have confidence in their knowledge, their work ethic, and their concern for patient welfare. Leaders will need to recognize this belief and accurately communicate the benefits of the new future state.

Another important role for leaders is to establish an environment designed to deliver high performance through the effective collaboration of all stakeholders. Efforts designed to address the often antagonistic relationships between physicians and administrators will be a necessary component of this effort.

The final ingredient noted by the author is the need for physician-leaders to support efforts to gather data on outcomes, analyze the data, and deliver meaningful results to all team members. The natural result of this will be to produce "rank lists" that order team members according to performance. Team members' natural reaction to being at the bottom of the list will be to request information about why they are ranked low on the list and what they need to do to improve. This should result in improved organizational performance.

A critical aspect of developing effective health care organizations is to engage physicians in the improvement process. An article that provided insight into this problem was by Lee and Cosgrove[90] in the *Harvard Business Review,* 2014. Important factors determining success of engagement efforts involving physicians include the articulation of a shared purpose, recognition of the importance of self-interest, providing leadership with respect for all stakeholders, and paying attention to institutional tradition. An important aspect of convincing physicians of the need to engage in a shared purpose is articulating an attractive goal, such as providing the best care for all patients. Once physicians are willing to discuss how such a goal is achieved, issues that may result in diminished compensation, and the complexities of the transition process, can be addressed. The authors stressed that an organizational policy that prioritizes doctors' interests over patients' interests in order to shield doctors from change in health care cannot be defended.

Appeals to self-interest can take the form of salary incentive plans, such as the one used in the Geisinger Health System, or by supplying physicians with detailed

performance data that will be used to determine contract renewals (this plan is used by the Cleveland Clinic in their evaluations of yearly physician contracts). Data can be used not just to improve performance, but to gain the respect of physicians who will not tolerate being defined as low performers. Respect is also gained when program changes are introduced gradually and input from physicians is sought regularly.

Lee and Cosgrove provided information on a variety of successful efforts to maximize recognition by physicians of institutional tradition. Gaining collective buy-in to support institutional behavior patterns is crucial for the success of this effort.

Recognition by health care institutions that change is necessary will immediately reveal the need to include medical staff as catalysts for change. An article that deals with this topic was by George and coauthors[91] in *Academic Medicine,* 2013. The authors emphasized the fact that a major problem leading to failures in the American health care system is lack of care coordination. One aspect of this problem is the failure of medical education to provide instruction in recognizing, organizing, and achieving changes that will improve care coordination. The authors identified the need for education in mechanisms of change and in improving conversations among staff that will support the change effort. The authors recommended that training and coaching in complex decision-making inside and outside of the realm of clinical care be offered to medical students and residents; additionally, they recommended formal training in leadership skills, including education to improve professionalism, interpersonal skills, and communication skills. Data cited by the authors confirmed the successful inclusion of such educational efforts in the entire continuum of education within the National Health Service in the United Kingdom.

One potentially useful avenue for developing future physician leaders of health care organizations would be a combined MD/MBA degree program. Patel and coauthors[92]described such a program in *Academic Medicine,* 2014. The authors surveyed graduates of a MD/MBA program over a 30-year interval. The data analysis showed that nearly half of graduates were involved in clinical practice rather than in administrative roles during the first decade after graduation, but this proportion dropped over time, with nearly 80% of graduates assuming administrative roles 21 to 30 years after graduation. Most graduates reported that the combined training program had benefitted their careers and assisted in the successful transition from practice to organizational leadership roles. The authors concluded that the program was successful, overall, but the results raised the question of whether migration from clinical care to administrative roles, if applied widely in health care, would decrease the availability of clinicians needed to provide patient care.

Business Aspects of Academic Medical Centers

The first article reviewed in this section of the overview provided insight into the features of academic medical center governance in an era where the balance between service and scholarship is critical to accomplishing the multiple missions of these institutions. The article was by Wietecha and coauthors[93] in *Academic Medicine,* 2009. According to the authors, common governance models include the "one leader" model, where a single individual is responsible to the university's president and board of trustees, or the "multiple leader" model, with governance divided among individuals, such as the university hospital CEO, the dean of the medical school, and the leader of the faculty practice plan. It was also mentioned that multiple leaders are often coordinated by a supervising chancellor or system vice president.

The authors noted that economic pressures have often stimulated the separation of the university hospital and the faculty practice plan from the medical school as the multiple leader model evolved. These changes occurred many times because of the need to protect revenue streams. The multiple leader model has led to conflicts over how to use revenue from clinical areas to support necessary educational and research functions of the academic medical center.

Wietecha and coauthors reviewed the various fund flow patterns that exist in academic medical centers. These include flows of funds from hospital and practice plans to faculty for salary support, as well as to medical schools for educational and research expenses—data cited by the authors confirmed that research is rarely self-supporting. Funds also flow in terms of overhead charges from hospitals and medical schools to the parent university, and

the authors characterized the discussions of fund flow allocations as notably contentious. The conflict that occurs in determining the best fund flow patterns is damaging to academic institutions and is one factor that has led to the adoption of single leader administrative models. According to the authors, this model does not guarantee that fund flow problems will be resolved without damaging conflict; because of this, the authors offered an alternative—that boards of trustees be chosen carefully and empowered to recruit the most effective leaders. These leaders would be charged with working collaboratively to accomplish the set of missions set out by the trustee leadership. This operational model can function successfully within a single or multiple leader model. The trustee leadership has to be provided with meaningful data that will permit an accurate progress assessment of all academic medical center enterprises. In settings where there are dual trustee boards overseeing the teaching hospital and medical school, it will be essential for the two groups to collaborate effectively. Each board will need to recognize and accept the merits of the respective sets of missions and buy into the cooperation that will be necessary to accomplish the missions.

Financial success of an academic medical center depends on developing and maintaining successful clinical service lines. Philips and coauthors[94]described one such effort in *Academic Medicine,* 2015. The authors stressed that creating and maintaining clinical service lines that provide team-based, patient-centered care is challenging due to the apparent conflicts with other aspects of the academic center's missions, including teaching and research, as well as the historical silo structure of the academic medical center. The authors described the factors that they believe ensure a successful service line, and stressed that participation by medical school and hospital leaders is needed, as is support for a full-time administrative and clinical leadership structure for the service line. These leaders must be given the authority to manage the service line and be held accountable for the creation and maintenance of processes that will assure excellent clinical outcomes. Cost data will need to be gathered and analyzed to provide the best information for determining success of the service line and stimulating change when needed. An important feature of a successful service line is the ability of all participants to be located inside the same center where the service is provided. This allows teams to be formed and to function effectively. In the study, all service line clinical staff participated in regular educational, training, and research activities so that the activities of each clinical area was well recognized by all caregivers.

In addition to the challenges previously listed, other obstacles in creating and maintaining a successful service line include cultural differences between participating groups, unclear reporting structures, and the steep learning curves for achieving needed administrative skills.

In order for academic institutions to consistently achieve high-quality clinical outcomes, these institutions need to support the development of faculty that is focused on delivering high-quality and efficient medical care. Rodrigue and coauthors[95]described one approach to achieving this in the *Ochsner Journal,* 2012. The authors completed a survey project to ascertain the baseline level of familiarity of faculty and residents with tools for quality improvement and promotion of patient safety. The survey also assessed levels of knowledge of quality improvement educational opportunities. A final section assessed the level of participation of residents in institutional quality improvement and patient safety efforts. The results of the survey indicated a need for formal training of faculty and residents in the art of teaching. Resident participation in quality improvement and patient safety projects was another obvious need, as well as targeted training programs that could help develop skills in analyzing and solving quality improvement problems.

The authors created several educational modules to achieve the learning goals that had been identified. They developed a system for integrating residents into ongoing quality improvement projects and organized teams of residents and faculty to actively work to incorporate patient safety practices into work environments.

Early results from implementation of the teaching effort and changes in organization to allow resident participation in quality improvement and patient safety projects have been encouraging, and the authors concluded that upcoming requirements from the Accreditation Council for Graduate Medical Education to provide education and experience in quality improvement and patient safety could be met with this approach.

I hope that the information provided in this issue of *SRGS* will help develop a working knowledge of the topics covered. Surgical conditions that require partial or complete splenectomy, as well as outcomes and complications of these conditions, will be presented in our next issue. I hope that you will join us for that discussion.

Thanks for reading *SRGS*!

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Editor in Chief

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CME Posttest | ETHICS, PATIENT SAFETY & THE BUSINESS OF MEDICINE

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1. Problems of "distributive justice" are encountered most often in which of the following areas of surgical practice?

a) Minimally invasive surgery
b) Vascular surgery
c) Transplant surgery
d) Robotic surgery
e) Plastic and reconstructive surgery

2. Each of the following is an important component of beneficence in surgical practice except which one?

a) Knowledge of the evidence supporting available therapies
b) Knowledge of the unique aspects of presentation of the clinical condition in the patient at hand
c) A thorough understanding of the patient's wishes
d) Knowledge of the patient's health insurance status
e) Technical skill to execute the needed procedure

3. The royal decree that created the Company of Surgeons in England was issued in which year?

a) 1671
b) 1855
c) 1848
d) 1745
e) 1914

4. Soon after its organization in 1913, the American College of Surgeons (ACS) addressed which of the following ethical issues?

a) Falsification of credentials
b) Fee-splitting
c) Failure to obtain informed consent
d) Development of a statement of ethical practice
e) Surgeon employment by hospitals

5. All of the following are fundamental rights of patients in the surgeon-patient relationship except which one?

a) The right to be adequately informed about care
b) The right to be treated by a competent surgeon
c) The right to have patient values placed above those of the surgeon
d) The right to refuse an operation
e) The right to have family present during the operative procedure

6. According to data cited by Suri and coauthors, the half-life of "truth" in the scientific literature is which of the following?

a) Six months
b) One year
c) 15 years
d) 45 years
e) 21 years

7. The "balanced" model of informed consent consists of which of the following characteristics?

a) A written form with the name of the hospital displayed prominently
b) Information relevant to risks, benefits, and alternative therapies is clearly presented
c) The surgeon writes the consent form in the presence of the patient
d) There is no written consent form
e) Consent is obtained from a relative of the patient

8. In the study reported by Classen and coauthors, the "global trigger tool" detected which percentage of adverse patient care events?

a) 90.1%
b) 8.9%
c) 1%
d) 14%
e) 42%

9. According to data reported by Steinberg and coauthors, the greatest discordance in the comparison of the University Health Consortium with the ACS NSQIP program occurred with which of the following complications?

a) Myocardial infarction
b) Surgical site infection
c) Pneumonia
d) Urinary tract infection
e) Bloodstream infection

10. Reliability of measures of hospital quality depends on which of the following?

a) Hospital size
b) Geographic location
c) Profit margin
d) Frequency of the outcome event
e) Proportion of medical staff employed by the hospital

11. According to the report by Studdert and coauthors, which percentage of malpractice claims did not involve medical errors?

a) 1%
b) 3%
c) 56%
d) 90%
e) 37%

12. The 2011 report by Jena and coauthors provided data suggesting that which percentage of surgeons practicing to age 65 would have a malpractice claim filed against them?

a) 21%
b) 99%
c) 75%
d) 32%
e) 6%

13. The study by Hu and coauthors showed that intraoperative deviations from care processes that increased risk of adverse patient events occurred with which frequency?

a) One per hour
b) One per 24 hours
c) One per week
d) One every 79.4 minutes
e) One every 15 minutes

14. Data from the study by Haynes and coauthors that compared patient mortality rates before and after introduction of the WHO Safe Surgery checklist showed a reduction in mortality from 1.5% to which of the following?

a) 0.1%
b) 0%
c) 0.8%
d) 1.4%
e) 0.3%

15. Available data suggest that the main factor responsible for improved outcomes after the introduction of the WHO Safe Surgery checklist is which of the following?

a) Having a printed checklist
b) Compliance with completion of all components of the checklist
c) Having the checklist completed by a nurse
d) Having a hospital administrator in the room during the procedure
e) Introduction of the checklist in a large number of hospitals simultaneously

16. The editorial by Fineberg asserted that the main goal of an improved health system should be which of the following?

a) Improved population health
b) Improved hospital profit margin
c) Full implementation of electronic health records
d) Conversion to a single-payer system
e) Universal access to immunizations

17. The major change in health system financing suggested by Emanuel and coauthors is which of the following?

a) Reduction of physician reimbursement by 25%
b) Increasing reimbursement for care provided by nonphysicians
c) Creation of mechanisms for determination of global payments at the state level
d) Increasing the number of hospital administrators
e) Locating all care of complex medical conditions in hospitals

18. Behaviors of hospital and health system boards that are associated with improved health outcomes include which of the following?

a) Increased board size
b) Number of corporate CEOs on the board
c) Strict financial oversight by the board
d) Emphasis on quality and gathering of quality metrics
e) Inclusion of medical staff members in board membership

19. The first retail clinic was opened in which state?

a) Georgia
b) Mississippi
c) New York
d) Indiana
e) Minnesota

20. Medicare payments for postoperative visits during a global period were discontinued for which reason?

a) Payments were going to a small percentage of surgeons
b) More postoperative visits were being paid for than were actually occurring
c) The proportion of payments going to surgeons in California was increasing rapidly
d) Funds were needed to support military operations
e) Hospitals were demanding increased payment for operative services

The following four questions are required by the American College of Surgeons for accreditation purposes. You must complete these four questions before submitting your answers.

21. This issue met the stated learning objectives.

a) Strongly agree
b) Agree
c) Neutral
d) Disagree
e) Strongly disagree

22. The content was relevant to my educational needs and practice environment.

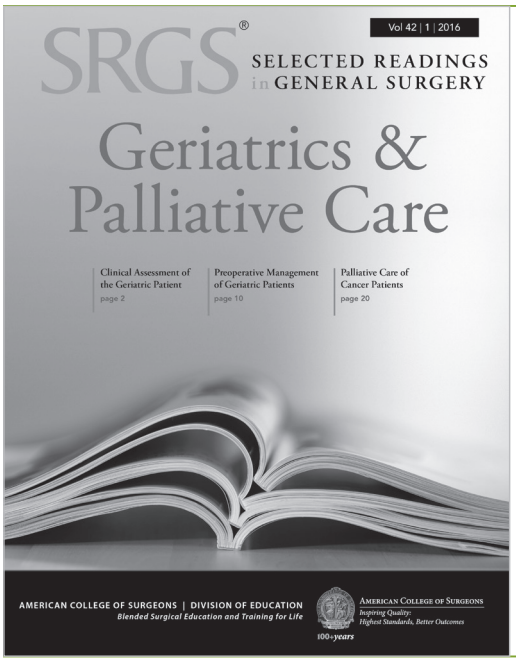
a) Strongly agree
b) Agree
c) Neutral
d) Disagree
e) Strongly disagree

23. There are potential barriers to incorporating what I have learned from this issue into my practice.

a) Strongly agree
b) Agree
c) Neutral
d) Disagree
e) Strongly disagree

24. The content was fair, objective, and unbiased.

a) Strongly agree
b) Agree
c) Neutral
d) Disagree
e) Strongly disagree



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Recommended Reading | ETHICS, PATIENT SAFETY & THE BUSINESS OF MEDICINE

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The *SRGS* Recommended Reading List is a carefully selected summary of current, classic, and seminal articles for further study. All of the articles below are cited in the order they appear in the literature review; they also appear in the reference list (43–46).

Full-text reprints of these articles are included in certain formats of *SRGS*.

1. **An organized approach to complex ethical cases on a surgical service…52-55**

   Wightman SC, Angelos P.

   The authors describe a useful approach to management of challenges in surgical ethics.

2. **Tragic knowledge: truth telling and the maintenance of hope in surgery…56-60**

   Suri M, McKneally M, Devon K.

   Valuable insights into the nature and the disclosure of medical "truth" are presented in this article.

3. **Professionalism, profession and the virtues of the good physician…61-67**

   Pellegrino ED.

   This opinion piece provides valuable insight into the elements of professionalism that are important in medical practice.

4. **Enduring and emerging challenges of informed consent…68-75**

   Grady C.

   This is a valuable article reviewing important features of the informed consent process.

5. **Another surgeon's error: must you tell the patient?…76-81**

   Moffatt-Bruce SD, Denlinger CE, Sade RM.

   This article reviews the pros and cons relevant to problems encountered in disclosure of information to patients.

6. **'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured…82-91**

   Classen DC, Resar R, Griffin F, et al.

   Data reported in this article suggests that chart review by qualified professionals identifies many more adverse patient events than are found by sentinel event reviews and discharge diagnosis analyzes.

7. **Claims, errors, and compensation payments in medical malpractice litigation…92-106**

   Studdert DM, Mello MM, Gawande AA, et al.

   Studdert and coauthors provide data that refute the notion that the majority of malpractice claims are frivolous.

8. **Protecting patients from an unsafe system: the etiology and recovery of intraoperative deviations in care…107-114**

   Hu YY, Arriaga AF, Roth EM, et al.

   The authors used video recordings of operations to determine the frequency and causes of intraoperative patient safety events. The data provide interesting insights that could lead to improved patient safety in the operating room.

9. **A surgical safety checklist to reduce morbidity and mortality in a global population…115-123**

   Haynes AB, Weiser TG, Berry WR, et al.

   This observational study conducted in eight hospitals provided data on an association between use of the WHO checklist and reductions in surgical mortality rates.

10. **Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial…124-131**

    Haugen AS, Softeland E, Almeland SK, et al.

    This cluster-randomized trial provides strong evidence for the beneficial effects of the WHO checklist on rates of postoperative complications.

11. **A systemic approach to containing health care spending…132-137**

    Emanuel E, Tanden N, Altman S, et al.

    Emanuel and coauthors offer insights into ways that healthcare costs can be contained while preserving or improving population health.

12. **Money and the changing culture of medicine…138-140**

    Hartzband P, Groopman J.

    In this editorial the authors present opinions on the effects of economic downturns on funding of health care.

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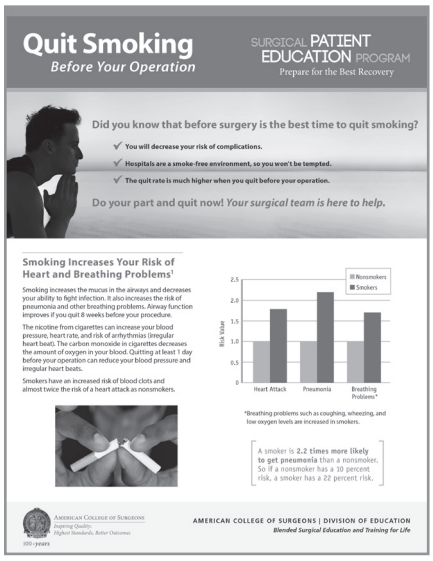

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