Ensuring Ethical Leadership in Academic Medicine

The American Surgical Association
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Leaders are the moral fiduciaries of each academic unit whether it be small, such as a clinical or research team, section, or division or large such as a department, college of medicine or health system. Ethical considerations are critical for the leader in academic medicine because ethics is paramount to leadership, primarily because leaders are responsible for establishing unit and organizational values and an ethical culture. The creation of an ethical environment benefits all members as well as all those who the department faculty serves, patients included.

Why is ethical leadership important? Morally upstanding leaders who believe in and promote ethics—the principles, standards, morals, values, and virtues that guide behavior in the academic world—have a substantial positive impact on an organization. This includes the faculty and employees and what they achieve, as well as the patients they serve and learners including students, residents, and fellows. Ethical leadership that strives to do what is right to advance the common good of academic medicine can not only improve their standing, effectiveness and culture but also make a difference in the community and beyond.

The most important factor in achieving an ethical culture is that it must be driven by the leaders at the top of the organization. It has been shown that ensuring an ethical culture is primarily determined by the leader’s character and personal values. In academic medicine, we are obligated to our core values to provide access to and deliver safe, effective, and high-quality patient care, top-tier education of students and residents, and safe and meaningful research. The success of our health care organizations is related to satisfying the obligations of the social contract between that entity and the people whom it serves. Furthermore, it is incumbent the leader to set a high moral tone for the organization in order to engender trust with the public, faculty, staff, and learners. Since academic organizations rely on public trust to be successful, it is critical that leaders establish and ensure an ethical culture.

Unfortunately, leaders may not be adequately prepared to establish and ensure an ethical culture or understand and anticipate the types of breaches that may occur, nor how to prevent and manage them. Some may opine that ethical leadership is based on common sense alone. Contrarily, others have learned that just as the leader must be prepared for negotiation, conflict resolution, personnel management, and finance, so must he or she also be prepared for ethical leadership.

We will examine the unique ethical challenges that leaders face in academic medicine and define the constructs of ethical leadership and an ethical culture. Our purpose is to provide strategies that will help leaders establish and ensure an ethical culture and to address ethical concerns more effectively when they arise.
We offer several disclaimers to readers. First, this monograph is written by surgeons. Although, the topic of ethical leadership is most likely similar across the array of medical disciplines, surgeons may provide a different perspective than if it had been written by a different set of physicians and specialists. Second, in order to demonstrate the types of ethical issues that may arise and to understand their genesis, we have selected case examples from the literature and press concerning ethical breaches and their management. All our organizations may experience such occurrences. The cases we have chosen are not meant to single out any single institution. Rather they have been selected for their potential educational value. In addition, we have created several fictitious case examples. If these cases are similar to real situations or people, this is purely coincidental. There will be examples of situations that have been handled well and others that were handled poorly. We hope readers will learn from each example so that they will be better prepared to manage ethical conflicts. Finally, the content herein is not meant to be a substitute for additional reading, education, and training in ethical leadership but rather it is a starting point.


Goals

Chapter 1: Provides the historical foundations of ethics and the evolution of bioethics, medical ethics, and surgical ethics. The foundation of ethical leadership rests on philosophical doctrines of moral right and wrong and moral good and bad.

Chapter 2: Defines leadership as the exercise of influence and power in a group context and distinguishes between leading and following. As patient care is a moral practice, physicians have unique attributes that prepare them for ethical leadership.

Chapter 3: Examines the construct of ethical leadership which is defined as the application of ethical principles and guidelines to leadership. Ethical leadership is justified by its many benefits. The lack of ethical leadership and poor ethical behavior is one of the more difficult challenges and organizational threats that we face today. Seven steps to achieve ethical leadership are presented.

Chapter 4: Explores the challenges of ethical leadership. These include the leader achieving balance and transparency with respect to the ethical burdens of power, privilege, and information management, as well as achieving consistent decision-making with acknowledgment of potentially competing loyalties and responsibilities. Case examples will be used to illustrate the challenges.

Chapter 5: Defines the key strategies to develop an ethical culture in your organization. Steps to accomplishing successful management include promoting an ethical culture reinforced by a code of conduct and alignment of faculty expectations with organizational goals. The principles of ethical decision-making (the foundation of an ethical culture) are discussed with case examples.

Chapter 6: Defines the domains and frequency of individual ethical breaches and the keys to successful management. No matter what type of ethical leadership you have in any environment, not just academic medicine, there will always be breaches by single individuals who disregard those principles. They will never be fully eliminated. One of the responsibilities of the leader is to respond and manage ethical breaches when they occur. Case examples will be used to illustrate challenges and management strategies.
Chapter 7: Focuses on the management of specific ethical issues that may arise in Human Subjects and Basic Science Research. We specify the ethical obligations of the principal investigator and co-investigators as well as research leaders. Leaders must establish and ensure a culture of research integrity based on published doctrine which must protect patient rights. A case example is used to illustrate the importance of patient rights.

Chapter 8: Examines ethical issues in data collection, analysis, and publication. Ensuring an ethical process begins and ends with the principle investigator and co-investigators. The leader’s role in ensuring integrity in this process can be circumvented by dishonest investigators that may go undetected until reported by a whistleblower. Hence, it is imperative that the leader establish a confidential system for reporting such violations and processes for managing them. Case examples are used to illustrate research fraud, how difficult it can be to detect and the subsequent negative consequences to the public. Issues in authorship and publication are discussed including the guidelines established by the Committee on Publication Ethics (COPE).

Chapter 9: Explores ethical issues involving the trainee. The ethical obligations of a mentor are provided. The mentor-mentee relationship is discussed, and we consider the six phases of mentoring. Unique issues in mentorship in the clinical trainee are highlighted by a case involving resident autonomy. The responsibilities for mentoring a research trainee are discussed. The chapter ends with the potential ethical issues in the mentor-mentee relationship.

Chapter 10: Discusses potential ethical issues involving faculty. We examine faculty compensation, conflict of interest with a case example and an in depth discussion of conflict of commitment with case examples. Finally, we look at the dual responsibilities of the physician leader to patients and the health system. This includes focusing on the leader’s challenges to balance discord between patients and health system.
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The Foundations and Principles of Ethics

KEY POINTS

• The term ethics refers to the philosophical study of the concepts of moral right and wrong and moral good and bad and any system or code of moral rules, principles or values.

• The history of ethics highlights its importance to every period in the history of humankind and in every culture and religion.

• Bioethics is generally more related to theoretical ethical issues and concepts surrounding all biomedical technologies, such as cloning, stem cell therapy, xenotransplantation, and the use of animals in research.

• Medical Ethics tends to be more specific and focuses on the medical treatments and needs of human individuals.

• Surgical Ethics is distinct from bioethics and medical ethics. It recognizes the rights of surgical patients, and the fact that the dyadic relationship between surgeon and patient is based on the role of authority of the surgeon due to his or her expertise and competence and the power of the patient to allow the surgeon to act on his or her body. Surgical ethics has five unique characteristics: rescue, proximity, ordeal, aftermath and presence.

Introduction

Herein, we will describe the foundations and principles of ethics as they apply to a physician in any leadership role. As a leader, a physician should be familiar with several dimensions of ethical principles. The first is Ethics as representative of Moral Philosophy. Secondly, as a physician and a leader in an academic position, he or she needs to be deeply acquainted with Medical Ethics, which refers to the application of moral reasoning to the setting of clinical practice and medical research. The third dimension is represented by Bioethics, which emerged in the 20th century, after WWII. Additionally, in the field of surgery, the
features of Surgical Ethics due to the unique traits of any surgical intervention, make it an important part of a leader’s ethical portfolio. The last dimension is Leadership Ethics, as a branch of the first mentioned dimension. It is defined by the same principles, but the focus is on the interplay of these pillars between leaders, staff, institutions, organizations and other strata.

Ethics

The term ethics refers to the philosophical study of the concepts of moral right and wrong and moral good and bad and any system or code of moral rules, principles or values. These last may be linked to virtually any group that is at least partially characterized by its moral outlook and concerns.

Ethics represents the disciplined study of morality. Whereas ethics refer to rules coming from an external source, morality refers to an individual’s own principles regarding right and wrong. Ethics comes from the Greek ethos which means character while morality comes from the Latin mos/moris, meaning custom, manner, behavior. Morality comprises the study of good and bad character and right and wrong behaviors and is ultimately a personal compass to guide good behavior. Character has to do with virtues and vices, meanwhile behavior or conduct is related to right and wrong actions. Right actions should be the goal of morality. Ethics is that area of Philosophy (also known as Moral Philosophy) which examines in a systematic way right and wrong moral behavior as well as moral concepts such as justice, fairness, virtue, duty. Different ethical theories provide an answer to the question “What is the greatest good?”

Ethics deals with the following:

The characteristics of individual and social good

• The nature of virtue
• Duty and moral obligations
• The freedom of will
• Right and wrong
• The analysis and assessment of human conduct
• Theoretical and practical ethical reasoning and decision-making

A Brief History of Ethics

Virtually every human society has some form of myth to explain the origin of morality. In Babylon, Hammurabi’s Code represented the first code of laws and ascribed to the “lex talionis” (“principle of an eye for an eye and a tooth for a tooth”). The Old Testament, important in the Jewish religion, provides an account of God’s giving the Ten Commandments to Moses on Mount Sinai. Christianity was based in part on “doing unto others as you would have them do unto you”. Hinduism underlines the qualities of virtue: self-restraint, inner purity, truthfulness, selflessness. Islamism was lavish in its contributions, specifically in the field of medical ethics.

According to Plato, there are some concerns with the view that morality was created by a divine power. In his dialogue with Euthyphro, he considered that there must be standards of right and wrong independent of the likes and dislikes of the gods, so it is not the divine approval that makes an action good.

Life in society requires constraints in behavior in order to adapt to life in a community. Many features of human morality could have grown out of simple reciprocal practices such as the mutual sharing of food and altruistic behavior. Kinship may be considered as a source for obligations and duties in every human society. In order to do so and to expect reciprocal behavior, one must choose a person(s) carefully to ensure reciprocity. In this regard, it is important to be able to distinguish between those who return favors and those who do not. It is part of human nature that each of us will tend to form stronger ties with those who reciprocate developing a bond of friendship and loyalty. Reciprocal relationships may be considered as a basis for determining, what is right and what is wrong, notions of fairness and the development of a system of punishment.
The current history of Ethics starts with the ancient Greek philosophers, mainly Socrates, Plato and Aristotle, and then was resurfaced by English positivists after the medieval ages, continuing with Hobbes, considered by many to be the father of modern Ethics. English and German schools have supported utilitarianism in contrast to Kantian ethics, respectively. Socrates (469 BC–399 BC) may be considered as the founder of Ethics as a branch of Philosophy. He contemplated that some problems can be resolved by data, like for example geometry, while others are moral issues, like the justice system. Some of his dicta are:

- Virtue is knowledge, hence it may be taught and learned
- He who knows must act accordingly
- Vice can only be because of ignorance
- No one voluntarily follows evil
- The highest attainable end of life is virtue

Plato (427 BC–347 BC) considered justice, wisdom, fortitude or courage and temperance as the four cardinal virtues. He placed justice at the highest level. He reasoned that we should acknowledge and provide the benefit of doubt as “No one knowingly harms himself or does evil things to others because that would harm his soul”. Aristotle (384 BC–322 BC) defined Ethics as Political Science and the highest of all sciences, since everything must aim at the good of the state. He developed a doctrine of means, wherein every virtue is a mean between two extremes, one an excess and the other a defect. Ethics is based on reason guiding action and moral choices. He considered that any rational action and morally virtuous action are synonyms and the purpose of mankind is *eudaimonia* (human flourishing).

During the medieval times there were predominantly two schools of thought: naturalism (ethical ideas arise from natural laws) and intuitionism (ethical ideas and obligations are intuitive). Thereafter, Descartes (1596–1650) and Spinoza (1632–1677) contributed with their concepts about truth.

Thomas Hobbes (1588–1679) considered the true doctrine of the Laws of Nature as the true Moral Philosophy: he is also well known for the detailed development of what has come to be known as the “social contract theory”. He is identified with deductive thinking, and his doctrine is founded on exclusive egoism ("ego being the soul"), represented by his dictum “man is the wolf of man”. Immanuel Kant (1724–1804) may be considered the most important and influential name in modern Ethics. He coined the term “the categorical imperative,” suggesting that “a person should act on those principles, such that when everyone act in that fashion, those principles become universal law”. Another Kantian formula is: “Act as to treat humanity, whether in your own person or in another, always as an end, and never as only a means”. He considers that freewill is based on the consciousness of moral obligations (“we ought, therefore we can”). Kant based his theory on three postulates of morality: the existence of god, the freedom of will and the immortality of the soul. Utilitarianism was founded by Jeremy Bentham (1748–1832) and considers that the ethical standard should be the greatest happiness of the greatest number of people. Nonetheless John Stuart Mill (1806–1873), through his essay Utilitarianism, developed this concept as a theory of ethics and foundation of morals, in which actions are considered right in proportion as they tend to promote overall human happiness, focusing on the consequences of actions and not rights, principles or virtues. According to Mill, the goal of ethics is to justify the utilitarian principle as the foundation of morals. This principle says actions are right in proportion to which they tend to promote overall human happiness. Thus, Mill focused on consequences of actions and not on rights nor ethical sentiments.

John Rawls’ “Theory of Justice” has been influential in Medical Ethics. He disputed the fact that the political and social organization is a community effort to achieve a maximum of good for all those in the society. He proposed an egalitarian point of view, attempting to resolve the questions and issues of distributive justice on the foundations of the social contract prevailing in the society.

**Medical Ethics and Bioethics**

Medical Ethics began in ancient Greece, with the Hippocratic Oath and so, has a longer history than Bioethics, which itself only really began after the Second World War, with the Nuremberg Code and the Helsinki Declaration. Traditionally, Medical Ethics, as the name suggests, represents the domain of physicians alone, in a self-regulating manner, especially when it addresses physicians’ behaviors.
Both Medical and Surgical Ethics may be considered as part of the realm of Bioethics (bios: life and ethos: behavior), term which was coined for the first time in 1926 by Fritz Jahr (1895–1953). He was a Protestant pastor, philosopher, and educator in Halle (Sajonia Anhalt, Germany) and in his article he developed the concept of “the bioethical imperative”, regarding the use of animals and plants in an extension of Kant’s moral imperative to all forms of life.7

Bioethics is considered the systematic study of the moral dimensions of medicine and the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting.8 In 1970, Van Rensselaer Potter (1911–2001), from the University of Wisconsin at Madison, was the first one to use the term Bioethics in North America. But in 1988 due to the use of this term by the medical community he decided to change to the term Global Ethics.9 In 1971, Andre Hellegers (1926–1979) a gynecologist from the Netherlands, founded the Institute of Bioethics at Georgetown University, which later became the Kennedy Institute of Ethics. There were opposite views about the topic within these two institutions from the beginning, but the latter prevailed in the medical field.10

Bioethics is an area of Philosophy concerned with ethical issues arising from biomedical scientific technologies, representing a field of applied and practical ethics. Although it is a relatively new field, it has been engaged in several challenging debates over the last few decades resulting from new medical technologies, as well as legal cases raising ethical issues which request and demand philosophical analysis amidst society and public demands. By its very nature bioethics should be multidisciplinary, including in its analysis representatives from diverse fields and backgrounds.

Bioethics and Medical Ethics have close ties, since it is possible to describe the latter as a field within, or branch of the former. However, the distinction between Bioethics and Medical Ethics deserves further clarification. Bioethics is even broader and is still mainly the domain of philosophers. However, throughout its development, it has influenced Medical Ethics. Bioethics is generally more related to theoretical ethical issues and concepts surrounding all biomedical technologies, such as cloning, stem cell therapy, xenotransplantation and the use of animals in research. Medical Ethics tends to be more specific and focuses on the medical treatments and needs of human individuals.11

The 20th century was plagued with unethical practices (Holocaust experimentation, Tuskegee Study, compulsory sterilization of confirmed “criminals, idiots, imbeciles, and rapists” specified in the 1907 Indiana Eugenics Law later to be found unconstitutional, Manhattan Project, among many others). However, the Nuremberg Code (1948), the 1948 Declaration of Geneva by the World Medical Association, the Helsinki Declaration (1964, 2013) and the Belmont Report (1978) paved the way to a major role of the ethical concerns in the medical research field. Of these, the Declaration of Helsinki is widely regarded as the cornerstone of human research ethics. The Declaration of Helsinki was originally adopted in 1964 and has undergone seven revisions the most recent in October of 2013. This document was the first organized effort to by the medical community to regulate research. The first revision in 1975 introduced the process of oversight of research by an “independent committee” which set the foundation for Institutional Review Boards in the United States and ethics review boards in other countries. In 1993, additional guidelines developed by the Council for International Organizations of Medical Sciences and the World Health Organization and were specified in their International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Interestingly, the first seeds of Medical Ethics can be seen in the Greek and Roman civilizations, followed by preeminent thinkers during the Medieval Ages.12 Medical Ethics started in ancient Greece with the teachings of Hippocrates of Cos (460 BC–370 BC). The Hippocratic Corpus is a collection of about 60 early Ancient Greek medical works associated with Hippocrates but not of his authorship. It includes works from the Cnidian and Coan schools of Ancient Greek medicine and contains detailed information in its different books and sections regarding ethical and moral behavior. It also contains a praise to the master or the teacher: “To hold him who has taught me this art as equal to my parents and to live my life in partnership with him …”, which emphasized the master-pupil model of training and teaching.

Plato (427 BC–347 BC) developed what may be considered as the first concept of informed consent, which at that time, only applied to free citizens: “The slave doctor prescribes what mere experience suggests as if he had exact knowledge; and when he has given his orders, like a tyrant, he rushed off with equal assurance to some other servant who is ill … but the other doctor, who is a free man, attends and practices upon free men, and he carries his enquiries far back and goes into the nature of the disorder, he enters into discourse with the patient and his relatives, and is at once getting information from the sick man, and also instructing him as far as he is able, and he will not prescribe for him until he has convinced him”.13
ENSURING ETHICAL LEADERSHIP IN ACADEMIC MEDICINE

Galen (129–199) practiced his science and art in Pergamon (present Bergama, Turkey) at the Asclepion temple, where he took care of injured gladiators and is considered one of the first hospitals for mental diseases. He strongly believed that physicians should achieve a deep knowledge of Philosophy. In the Islamic world the name of Avicenna (980–1037) was influential in the field of medical ethics. In the 9th century, Al Ruhawi defined the two necessary conditions for the medical practice of a physician: ethics, which is appropriate to the profession, and scientific competence. Maimonides (1135–1204) was a Talmud scholar and a recognized physician, and a great forefather in this field.

John Gregory (1724–1773) should be considered as the father and developer of modern Medical Ethics. He was professor at the University of Edinburgh and a product of Scottish Enlightenment, and the one responsible of transforming Medicine from a trade into a profession. His “Lectures upon the duties and qualifications of a physician” introduced the concept of Medicine as a fiduciary profession and the physician as a moral or fiduciary agent. He defined Medicine as “the art of preserving health, prolonging life, treating diseases and making death easier”.14

However, the term Medical Ethics was used for the first time by Thomas Percival (1740–1804), when requested to prepare a methodology of professional conduct relative to hospitals and other medical charities, due to the opposition between Tory surgeons and Whigs physicians at the Manchester infirmary. His paper was published in 1803 as “Medical Ethics, or a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons”. Interestingly, the tentative title of his contribution had been “Medical Jurisprudence”, based on Justinian’s dictum about the precepts of law: “Live morally, hurt no one and give to each other his due”. Medical Ethics is organized in four sections dealing with: duties regarding hospitals, professional behavior in private practice, relations with pharmacists and duties relative to the legal system.

Meanwhile in America, Samuel Bard (1742–1821) pointed out the virtues of integrity and ability, condemning ignorance and dishonesty. Worthington Hooker (1806–1867), vice president, of the American Medical Association, was strong advocate of medical ethics and promoted a sound and trustworthy patient-physician relationship.15

Sir David Ross (1877–1971) was an English philosopher and the first to describe the so-called prima facie ethical duties: faithfulness, compensation, gratefulness, achievement of the highest good and nonmaleficence.16 Based on Ross’ deontological ethics, Beauchamp and Childress described the four ethical principles which guide medical ethics: respect for autonomy, beneficence, non-maleficence and justice.17

Surgical Ethics

Sir William Stokes (1838–1900), a past president of the Royal College of Surgeons of Ireland, was the one to first use the term Surgical Ethics, while speaking about unnecessary surgical procedures at the Meath Hospital.18 This may have been prompted by the introduction of general anesthesia which represented a substantial advance for the field of surgery in that more procedures could be done, but was associated with a high mortality rate in its early application. The introduction of anesthesia generated a hot debate regarding its moral acceptance, due to the risks, problems encountered and unacceptable complications. Since pain and suffering were considered, from a religious approach, a punishment for sinful or incorrect behaviors, the introduction of anesthesia generated plenty of moral discussions.19

The concept of professional diligence as a core foundation for medical and surgical ethics was reintroduced by Richard Cabot (1868–1939), professor at Harvard University, with the goal of learning about medical errors from the assessment of autopsies. He was a pathologist and a well-known researcher in the field of medical errors and should be credited with introducing what is known as “an ethics of competence”. Under the influence of the Chicago surgeon Franklin Martin, the American College of Surgeons was founded in 1913 with “the mission to standardize surgery for the benefit of the profession and the protection of the public”. Surgical competence, itinerant surgery and fee-splitting were some of the hottest topic to confront and deal with.20

The appearance and later development of organ transplantation presented new ethical challenges, as an example of surgical innovation and the new topics which surround its appearance: brain death and its definition, allocation of resources, how to deal with insufficient donors, among others.
The domain of professionalism also has raised the standards and concern for medical ethics, since a good professional is expected not only to excel in the art and knowledge of the profession but also to fulfill the ethical obligations imposed by codes of conduct and societal norms expected by patients.

McCullough et al. were among the first to examine the scope of Surgical Ethics, which they defined by the way in which the procedural nature of Surgery and its capacity for bodily and psychic impact modify general ethical considerations such as virtues, consequences, rights, justice and equality. Their point of view is that the Ethics of Surgery or Surgical Ethics is a special case of the general Ethics of Medicine. They also contemplated the fact that Surgical Ethics recognizes the rights of surgical patients, and the fact that the dyadic relationship between surgeon and patient is based on the role of authority of the surgeon due to his or her expertise and competence and the power of the patient to allow that upon the body of an individual, a surgeon may act.

Little defines the five categories which explain the fact that Surgical Ethics may be considered apart and unique. Those categories are rescue, proximity, ordeal, aftermath, and presence, which underline the surgical patient's experience. The patient's initial step is a need for rescue from a surgical condition, which may be emergent or not. When trying to choose a surgeon, their need brings surrender, which of course does not mean annihilation. Proximity deals with the intimate relationship between the patient and his or her surgeon. The ordeal and the aftermath refer to the short-term and long-term experiences of suffering after the surgical procedure is performed and the patient recovers. They involve, among others, pain, and scars as well as the psychological impact of the operation and the postoperative recovery. Presence underlies the path which is traversed by surgeon and patient in an intricacy of feelings and closeness.

Surgery, in contrast to other medical specialties, deals with unique features:

- Surgery harms before it heals, in the sense that any surgical attempt needs due justification so as to not consider a surgical intervention as a felony to an individual.
- Surgery is invasive as stated before, so the requirements for an informed consent process are more stringent. As Judge Benjamin Cardozo stated in his 1914 ruling: “A surgeon who performs an operation without the patient’s consent commits an assault” (Schloendorff vs. Society of New York Hospitals).
- Surgery is characterized by fallibility, and 40 to 60% of all medical errors are considered to happen in the operating room.
- Surgical decision-making is mostly performed under conditions of uncertainty.
- Surgery is prone to risks, complications, accidents, and sequelae.

An extraordinarily strong trait of the surgical demeanor is represented by the surgeon’s accountability, this sense of personal and moral responsibility for the well-being of the patient. As Bosk stated: “When the patient of an internist dies, the natural question his colleagues ask is “What happened?” When the patient of a surgeon dies, his colleagues ask, “What did you do?” By the nature of his craft and his beliefs about it, the surgeon is more accountable than other physicians and he also has much more to account for. Of course, this is not all to say that every time a surgical patient dies the surgeon is at fault, only that it is much harder for him to claim that he had no hand in it than it is for other colleagues.

Surgical Ethics combines and provides a frame for solutions to all the issues, problems, decisions, conflicts, and dilemmas a surgeon encounters in the daily activity of patient care, surgical research, surgical education and training, leadership, and management. It should be considered as a discipline of both Ethics and Surgery which gives an answer to the question: “What ought morality to be in Surgery?”. All the issues related about good professional practice are within the domain of Surgical Ethics more than related with surgical technique; however, it should be the rule that being an accomplished and competent surgeon is preliminary to the fact of being an ethical one.

The gordian knot in Surgical Ethics has evolved through modern times. It is no longer “What can we do for this patient?”, but “What should be done for this patient?”. This change in paradigm reflects the focus on the ethical dimension that requests a surgical care centered in the patient. As Pellegrini said: “Surgery is a moral practice and every surgeon is a moral agent”. In the last fifty years the role of Surgical Ethics has changed drastically, lying in present times at the core of surgical professionalism.
Thus, the ethical practice of Surgery implies dignity, tolerance and respect, and as such it means: a) placing the welfare and rights of the surgical patients above one’s own, b) treating each patient as one would wish to be treated, c) valuing each individual and d) doing unto others as one would have them do unto us. From this list, some basic rights inherent to patients who need surgery emerge:

- The right to be adequately informed about the benefits and risks of the proposed surgical treatment
- The right to be treated by a competent surgeon
- The right to have his or her health valued higher than the surgeon’s own economic interest
- The right to decide whether to accept treatment
- The right not to be killed intentionally or negligently
- The right not to be harmed by intent or negligent
- The right not to be deceived

Every time a surgeon is confronted to a surgical decision, he or she will go through a two-part process: distinguish “How to treat?” questions, which are a topic of medical and surgical science from “Why to treat?” questions, which are linked to Surgical Ethics and so, should be based in moral philosophy. When deciding on “Why to treat?”, Surgical Ethics provides us with the four principles: beneficence, non-maleficence, respect for patient autonomy and justice. The ethical surgeon, the one who is diligent and achieves surgical competence, will display the role of a fiduciary agent, that holding the character of a trustee, who in respect to the trust and confidence deployed on him or her, acts primarily for another individual benefit in matters connected to that understanding. In the particular case of a surgical patient, in his or her benefit and wellbeing. It becomes clear that the surgeon-patient relationship is based on fiduciary responsibility rather than characterized by a contract. In this relationship, the surgeon carries a role “as authority” by virtue of training, expertise, wisdom and concern for the patient, meanwhile the patient holds a position “in authority”, being able to consent and thus allowing that an operation upon him or her be performed. The patient-surgeon relationship is the key to the ethical care of the surgical patient and the link of proximity between the patient and the surgeon is defined by the trust deposited in that dyadic relationship.

In the conflict between altruism and self-interest, which is the initial conflict which any surgeon or physician are exposed to, the first one must prevail.

The field of Surgical Ethics is represented primarily by the study and analysis of topics such as the doctor-patient relationship, the surgical informed consent process, patient’s competency and autonomy, surgeons’ diligence and competence, surgical indications, innovation, truth-telling and candor, quality of life, end of life issues and surgical futility, fairness in resource allocation. Nonetheless it overviews all the aspects and relationships a surgeon establishes in his or her activity in the patient care arena, the academic field, with colleagues, leaders, fellows, residents, medical students and mentees and with society as a whole.

References

Definition of Leaders and Followers

**KEY POINTS**

- Leadership is the exercise of influence and power in a group context in order to achieve common goals.
- The definition of leadership is incomplete without distinguishing between leading and following.
- Leaders are sometimes followers and followers are sometimes leaders depending on the context.
- The unique features of medical training which emphasize duty and moral obligations to patients and society prepare a physician for ethical leadership.
- Patient care is a moral practice and the physician’s role as a moral fiduciary is at the core of medical ethics. Hence, physicians have unique attributes that prepare them for ethical leadership.

**Introduction**

In general terms, leadership is the exercise of influence and power in a group context in order to achieve common goals. In most academic health centers, there is a well-defined leadership structure amongst the various components of the enterprise as well as teams of leaders to coordinate activities across the organization. Regardless of the size of the unit, an executive is responsible for the alignment of that unit with the larger organization as well as day-to-day management of the unit. The leader must manage faculty and staff in the unit, the followers, but ultimately is responsible to her or his superiors for performance of the unit. The leader is the agent of change for that unit and is engaged in the coordination of the vision, goals, and culture for the organization. To succeed, a team based on strong collegiality and mutual respect is necessary. Furthermore, the leader has the major responsibility of promoting the needs and wants of their followers and their organization or service unit. A leader may be at the top of an organization/unit or just the leader of subunit or division. It is no different in health care where the leaders may be presidents, CEOs, deans, chairs, division chiefs, section leads, or on a smaller, but equally important level, the leader of “the code blue team”, a consult service or an operating room team. The organizational structure in academic health centers is unique to each organization. Indeed, it has been frequently noted that “if you have seen one academic health center (AHC) you have seen one AHC.” In general, the structure is extremely complex and involves a health system, a college of medicine, departments, divisions and centers and institutes which serve as multidisciplinary clinical or research units designed to foster greater
collaboration. In defining your role as a leader in an organization, it is critical for you to know the organization’s structure and its operating system for day-to-day management, defining the boundaries of your authority and limits on your authority. At times, you will have autonomous authority to make decisions but not always. It is prudent to learn when you do not and when you need to seek higher approval. All leaders will be followers as well within the broad structure of the organization.

The definition of leadership is incomplete without distinguishing between leading and following. The leader usually is given the credit for success and responsibility for failure. For example, a department chair in surgery will usually get credit for improving the mortality index, increasing surgical admissions and surgical volume, but criticized and accountable for correcting a high readmission rate or suboptimal financial performance. In fact, we know that in either circumstance the outcome is the result of efforts of many department members who are followers. Leaders and followers work together in complementary roles. The leader takes on the responsibility for the direction of a group. The followers implement the plans and do the day-to-day work. Leaders through their actions affect followers’ lives either negatively or positively. Hence, the leader has a moral responsibility to the followers and consideration of leadership through service. A goal of moral leadership is to develop and build more leaders, not produce more followers.

Leaders are sometimes followers and followers are sometimes leaders. In other words, they switch roles depending on the circumstances. For example, a division chief of vascular surgery is responsible for the clinical outcomes, patient satisfaction, and career development of his or her followers, but is a follower in relation to the department chair. The leader—follower continuum is dynamic and changes depending upon the circumstances and associated momentum.

The Academic Physician As a Leader

Academic physicians will be asked to lead teams. However, the size and complexity of the team may vary. In some circumstances the physician is overseeing daily patient care. For example, the trauma surgeon is the leader of the team responding to a trauma alert, in the operating room the surgeon is responsible for the coordination of care of the surgical patient, and on rounds the Chief Resident is the leader of a smaller team of students and post graduate trainees providing perioperative care. Each physician-patient relationship involves some element of leadership. The physician acts as a fiduciary of information and trust for patients as they go through the treatment process.

In other circumstances the academic physician leader has a larger scope of responsibility: for example, a clinical department, division, research program, college of medicine, or even a large healthcare system. In these circumstances, the physician will have responsibility for diverse programs, organizational outcomes and metrics in patient care, research, education and financial performance. Regardless of the scope, size or complexity of the organization, the principles of ethical leadership are fundamental to the success of the leader, his or her followers and the organization or unit.

The Distinctive Attributes of the Physician As a Leader

One could assume that a physician leader is like all other leaders and offers no distinctive attributes. However, the features of medical training which emphasize duty and moral obligations to patients and society prepare a physician for ethical leadership and argue against that assumption. Society requires the physician leader to embrace a role as a moral leader: who inspires our values in words and actions and leads by example. It means we stand for equity for the most vulnerable and voiceless among us and support truth, reason, and science. The physician-patient relationship is unique and bound by duty and trust. Based on training and experience, a physician brings a unique skill set and ethical foundation which likely influence their thought processes in leadership roles.

Patient care is a moral practice and the physician’s role as a moral fiduciary is at the core of medical ethics. The physician-patient relationship is a bond characterized by trust. As a moral fiduciary the physician is bound to focus on the patient’s best interest, protect and promote that interest and only secondarily be concerned with her or his own interests. By the nature of his or her training the physician develops a moral character built upon the foundation of medical ethics. Hence, the physician as a leader by training and experience has been exposed to the personal values and responsibility necessary to be an ethical leader. Albeit we are human and the natural drive for personal gain can derail the ethical core. Hence, the academic physician as well as other leaders should be very attentive to the ethical dimension in every aspect of leadership and decision-making.
The Construct of Ethical Leadership

Ethical leadership is the application of ethical principles and guidelines to leadership. It is a guide to manage the role and the activity of a leader. Since Ethics deals with concepts of right and wrong as well as virtue, it follows that ethical leadership is defined as influencing and leading people by virtue and ethical principles through example and instruction, with a clear knowledge of what is right and what is wrong. Plinio et al. highlighted the lack of ethical leadership and poor ethical behavior as one of the more difficult challenges and organizational threats we face throughout multiple organizations today.¹

Ethical leadership may prevent these issues, with a focus on trustworthy leaders in the context of servant leadership. The concept of servant leadership was proposed by Greenleaf.² Although the autocratic and absolutist King Frederick II of Prussia, known as “Frederick the Great” (1740–1786) portrayed himself as the “first servant of the state”, the most important trait in being a servant leader is making the leader’s main priority to serve rather than to lead, promoting success and power in the growth of others. A trustworthy and effective leader should aspire to be a morally virtuous individual, one who respects the moral codes enjoining honor, justice, charity, fairness, mercy, temperance, and all the qualities opposite to vice.
Ethical leadership often takes the form of three separate approaches. The three have historical and philosophical foundations and all of them emphasize different aspects in decision-making:

1. One approach follows Immanuel Kant’s idea of doing the right thing, or following the moral imperative, coming from the understanding of what is right and what is wrong and thus making the right decisions. This approach to leadership is based on the proper means, following the rules of virtue and good action.

2. Another approach is related to the utilitarianism theory, maximizing the welfare and benefit of the organization and its individuals. The major concern focuses on the proper ends of the action, not necessarily on how you get there. This approach is closely associated with John Stuart Mill and the ethical cost-benefit analysis.

3. The last approach focuses on the theory of libertarianism, by which the leader protects the freedom of the individuals as the main concern. The concern is on the intent of individuals. The approach follows Aristotle’s idea of virtue ethics or eudaimonism, a moral philosophy that defines right action as that which leads to the well-being of the individual, thus holding well-being as having essential value.

In the modern context, ethical leadership often emphasizes either one of the above or a mixture of the three. What is required of an ethical leader is to act and lead in an ethical way, meaning ethical leadership is both visible and invisible: act with an ethical behavior and think in an ethical manner. Ethics should be an integral part of the framework. Many authors speak about the “four Vs of ethical leadership” represented by vision, values, voice, and virtue.

In the words of Brown and Treviño, “ethical leaders explicitly focus attention on ethical standards through communication and accountability processes”, this aspect differs from authentic, charismatic and transformational leadership. Thornton recommends the following seven steps to achieve ethical leadership as well as an ethical framework in an organization:

1. Facing the complexity of ethical decision-making
2. Not separating ethics from business but including ethics in every business activity
3. Not allowing negative interpersonal behaviors to erode trust
4. Seeing ethics beyond laws and regulations
5. Not exempting subordinates from ethical expectations
6. Celebrating positive ethical moments
7. Understanding ethics to be a long-term development

The traits an ethical leader needs to hone and enhance are:

1. Conscientiousness: strong moral identity doing the right thing and thinking what the right action ought to be and act accordingly
2. Inclusiveness
3. Accountability
4. Consideration
5. Consistency
6. Authority: which is not a synonym of power
In summary, the three pillars of ethical leadership are related to virtue ethics and compounded by the following:

- Be the example
- Focus on the overall importance of ethics, including ethical standards, behaviors and issues
- Communicate in an effective and efficient manner

References

The Challenges to an Ethical Leadership in Academic Medicine

KEY POINTS

• The challenges of leadership include the management of power, privilege, and information, and attainment of equipoise in consistent decision-making and while balancing loyalties and responsibilities.

• Power may be classified as formal (legitimate, coercive, and reward based) and personal (referent and expert). The crucial decision for the leader is to decide what types of power he or she should use, in what situations, and for what purposes.

• Becoming an effective leader requires one to consider and reflect on material privilege and privileged identity and how these relate to leadership and are viewed by and effect followers.

• As a result of involvement in decision-making, leaders have more access to information than do others in an organization. The leader is a fiduciary of information and must consider when and how much information to share.

• An effective leader makes decisions in a consistent and fair manner devoid of favoritism and bias even under conditions of uncertainty.

• An effective leader is challenged to equitably manage competing loyalties.

• A leader in Academic Medicine is responsible to many stakeholders including the public, the organization, faculty, staff and learners. He or she is responsible for establishing processes that enhance and maintain a “psychologically” safe environment for employees, faculty, learners and patients, manage scientific misconduct, ensure compliance with Medicare billing and HIPAA regulations and other healthcare regulations and assure appropriate credentialing for privileges.
Introduction

Craig E. Johnson in his book entitled *Meeting the Ethical Challenges of Leadership: Casting Light or Shadow* describes the six burdens of leadership: power, privilege, information, consistency, loyalty, and responsibility.¹ These burdens are the primary ethical challenges that the leader must manage in order to be effective and to keep an organization balanced and avoid ethical crises. The challenge of ethical leadership is the dynamic management of these dimensions. The illustration in Figure 4-1 emphasizes that the leader must maintain balance in managing these challenges. The management is impacted by a leader’s style and character and his or her ability to make ethical decisions. Failure to reach equipoise and balance can lead to an organization that may be unable to realize the level of trust needed to grow and sustain an enterprise. The symptoms of a potentially unethical organization in health care include the following: pressure to maintain numbers at all costs, lack of engagement with stakeholders who display fear and silence, a bigger-than-life CEO, a weak board, unchecked conflicts of interest, and arrogant innovation.²

Each of these challenges and the ability to make ethical decisions are important in every domain of the academic leader’s responsibility including management of: 1) faculty and staff, 2) education of medical and postdoctoral, students, residents, and fellows, 3) research in basic science, clinical trials and health services, 4) clinical care and 5) finance. Understanding the dynamic interplay of these challenges and the principles of ethical decision-making should help the leader in an academic health center to better navigate their responsibilities and be a more effective and ethical leader.

**FIGURE 4-1:** Effective ethical leadership requires the leader exercise dynamic and balanced management of the six major challenges in order to create a culture of trust. To do so, the leader must rely on her or his character and meet the duties of leadership. Failure to do so can lead to organizational imbalance and dysfunction as signaled by the cardinal symptoms: pressure to maintain numbers, lack of trust and engagement with stakeholders who display fear and silence, a bigger-than-life CEO, a weak board, unchecked conflicts of interest, and arrogant innovation. (Published with permission of E. Christopher Ellison, MD, FACS.)
Power

Definition and Classification

Power is defined as the capacity or ability to direct or influence the behavior of others or the course of events. It is how a leader operationalizes authority and influence. Leaders make use of various power bases in day to day management. French and Raven classify power as formal power (legitimate, coercive, and reward) or personal power (expert and referent power). An effective leader makes use of both formal and personal power. Formal power allows one to initiate and control whereas personal power allows one to plan, organize and persuade.

In reference to a leader, power may be based on one’s position. According to French and Raven, this type of formal power is termed legitimate power. It is power that comes from an organizational hierarchical structure in which the leader directs or influences the behavior of others because of his or her position (i.e., Chair, Division Director, Dean, CEO, etc.). This type of power allows the leader to act as such and initiate action.

The second type of formal power is termed coercive power. It occurs when a leader punishes subordinates or followers for not meeting performance expectations or deters an individual from making decisions that will negatively impact the organization. Health systems frequently use coercive power to encourage physicians to complete charting or complete required learning modules. Failure to complete the requirement may result in a monetary fine or loss of computer network access. Another example is the loss of OR first case start time if a surgeon is repeatedly late and his or her patients consistently are not ready for surgery (no consent or preoperative testing and history and physical examination). A third example may occur when a physician seeks to open a clinic at a site that is not within the planned footprint of the organization and not part of the strategic plan. In this circumstance the leader may intervene to stop the faculty member from proceeding.

The third type of formal power is reward power. It occurs when a leader gives a subordinate(s) reward for high levels of performance. Rewards may be monetary such as a bonus, or recognition and praise.

Whereas, legitimate power allows a leader to initiate change, to hire, and to create and sustain programs, coercive power and reward power allow a leader to exert control over an organization and subordinates. All three may be in use at any given time.

The first type of personal power is termed referent power. Leaders who are likeable and trustworthy and who a subordinate may wish to use as a role model have referent power. The leader may use this relationship with subordinates to influence their actions. Leaders who are affable and trustworthy are more likely to be able to lead an organization through difficult times. The second type of personal power is termed expert power. This is based on the perceptions of subordinates concerning the leader’s expertise and competence. A confident leader with a track record of success is naturally easier to follow. Personal power allows a leader to plan, organize and persuade.

Management of Power

The effective and ethical leader modifies the application of power in carrying out his or her authority and influence. However, the more unchecked and unregulated a leader’s power is, the more risk there is for abuse. As Lord Acton stated, “Power Corrupts and absolute power corrupts absolutely”. In health care, there are few leaders that have completely unchecked power and control. Most of these organizations have a governance structure such as boards or a hierarchical structure that modulates a leader’s authority. The CEO of a medical center reports to a board. The medical school dean has direct report to the provost or university president and ultimately to a board of trustees. The chair of a department reports to the dean. It is important to appreciate that most leaders in large health systems, colleges of medicine, or departments in fact function as middle managers. They have a direct report to a superior and governing body and have responsibility to the faculty and staff in their unit. For example, the chair of a department reports to the dean and must satisfy the needs of the faculty to be successful.

Still, unmodulated power is a risk for the organization. For example, a leader who is isolated and does not engage the organizational community and other leaders will be viewed as dictatoral. Contrarily, a leader who develops a management team representing various components of the organization and engages them in decision-making processes will be viewed as far more collaborative and transparent. In a department of surgery, this leadership team may consist of vice chairs, division chiefs, as well as a large faculty. The inclusion of the latter is critically important and signals that the leader wants the input of the organization and that the leader realizes that collaboration is critical for success.
In exercising her or his authority, the crucial decision for the leader is to decide what types of power to use, in what situations, and for what purposes. In addition, the leader must consider how much authority to delegate. Delegating authority is highly motivating and amazingly effective at promoting collaboration and organizational trust. It is a powerful tool used to achieve follower engagement as well as develop future leaders. However, with delegation comes some risk; the amount of which depends on the level of experience of the person(s) to whom the authority is delegated. Hence, there is the need to develop accountability measures and outcome metrics to assess performance to enhance the effectiveness of the management team.

**Privilege**

**Definition**

Privilege is a special advantage not enjoyed by everyone. Privilege comes from Latin *privilegium*, meaning “a law for just one person”, and can be interpreted as a benefit enjoyed by an individual or group beyond what’s available to others. It is essential to the construct of ethical leadership to understand that the word “privilege” can often take on a different meaning regarding leadership. Although people may shy away from discussions about privilege in leadership, becoming a great leader means being able to navigate those responsibilities and conversations even when they make one uncomfortable.

Traditionally, the word privilege has centered on the advantages and immunity that people inherently have because of certain aspects of their leadership role and identity. Superficially, this may be equated to receiving greater compensation, benefits, and office size. This is a fact of life. Some would say with leadership comes great privilege.

Another point of view is that with privilege comes leadership. The privilege of identity often plays a role in how—or if—someone is offered or permitted to take on certain leadership opportunities. If one does not have the privileged identity, then he or she may not have the opportunity to lead. In addition to identity, privilege is about access and those who have the power to provide that access within the organization. Most of the people who have access to leadership often reflect privilege in their personal identity and sometimes harbor it for their own benefit.

**Managing Privilege**

**Material Privilege**

Material privilege refers to tangible assets or benefits that come with leadership. It is best to manage these at an arm’s length by establishing processes and clear formulas for setting compensation and awarding incentives. In the best of circumstances, compensation and benefits of the leader should be determined by a third party such as a board of trustees or directors or compensation committee. This can mitigate the perceived inequality of a leader’s compensation and benefits.

**Privileged Identity**

One way leaders fail is by not acknowledging the privilege and power their role affords them. When anyone decides to take on a leadership role, they’re making a statement—whether they verbalize it or not—that they’re taking responsibility for the development and care of someone else’s experience. As a leader, one should reflect about what “privileged identity” means and how you may have benefitted from it.

Examining one’s privilege can prove difficult. In so doing, it is important to recognize that the issue is never about someone simply having privilege, but about what she or he does with that privilege. Introspection is necessary for one to understand how an organization can expand opportunity beyond those with “privileged identity” to make it more equitable and diverse. This means setting an example that includes investigating what privilege means in your medical center and how you and other leaders benefit from it and how you can help others break the barrier to access the same opportunities. Recognizing that a “privileged identity” provides access to leadership roles, allows one to step back and create opportunities for others who do not have the same privileged access. This can change the balance of privilege in an organization resulting in richer engagement and the potential for new and diverse leaders to emerge.3
For example, although women make up at least 50% of our medical school graduates and an increasing percentage of our faculties, women make up a small portion of department chairs. Deans and organizations that are sensitive to the realities of “privileged identity” will appreciate this and take steps to identify women candidates for new chair positions. In addition, they may take steps to include disproportionate weighting of female gender on search committees and incorporate training for unconscious bias for all search committee members. An ethical leader must also be sensitive to the lack of a “privileged identity” in underrepresented minorities in medicine and take proactive steps to correct this inequality.

**Discrimination and Racism**

The killing of George Floyd by Minneapolis police on May 25, 2020 has greatly distressed us all. This has focused many leader's attention on systemic racism and social injustice and prompted many to ask “are we doing enough” to eliminate discrimination and racism in our hospitals and medical schools. Unfortunately, the answer is no. The ASA 2018 report Ensuring Equity, Diversity, and Inclusion in Academic Surgery (see Chapter 6), describes the negative effects of bullying, harassment, sexual harassment and diversity driven microaggression, on the professional environment of surgery; to define the scope and nature of these problems; and to recommend policies and leadership practices that will create a culture of respect, equity and inclusion.

To make cultural changes to eradicate discrimination and racism in academic medicine, leaders, faculty, and staff are encouraged to learn to be an upstander. Our professional codes of ethics and definitions of professionalism have not been effective in eliminating discrimination, sexual harassment, and racism. People are very aware that such behaviors do occur, yet we do not know how to intervene when we witness such behaviors. Microaggressions and bias are more difficult to discern. To address these issues, a leader’s action plan becomes both to increase awareness of adverse behaviors and to a greater extent train faculty and staff to be an “upstander”. Being an “upstander” is generally the work of those not commonly targeted such as those with privilege. Being an “upstander” or “active bystander” means going further than simply not discriminating, it means calling out discrimination when you see it and actively supporting those minorities underrepresented in medicine and women. This is a small but powerful step to reign in these adverse behaviors. This is an action that a leader should personally emulate and by so doing set an example for their organization and thereby inject this as a standard into an organization’s culture. Unfortunately, our medical and surgical culture as it relates to reporting, accountability, and consequences for the perpetrator of discrimination and racism is severely lagging the pervasiveness of these events. Leaders have the responsibility to create a transparent, supportive, and safe culture for reporting and a graded system of accountability that has real consequences for these offenders regardless of their privilege and entitlement.

**Information Management and Communication**

**Definition**

When one speaks of information one immediately assumes information technology, electronic health records, and restricted data. These are all very important for the leader. Regarding ethical issues, perhaps more important is communication about events that occur within an organization. A leader has more access to information than others in an organization. They are more likely to work with leaders of other units in the strategic planning process. They have access to medical center financials, quality measures, safety issues, and personnel files. In addition, they will have access to Information that is potentially harmful to the medical center but may be important to share with the public. Information access is another privilege associated with leadership. The leader is a fiduciary of this information and must consider if, when, and how much to share.

The challenge to an ethical leader is to meet the societal responsibilities while managing potentially critical organizational situations. If the information could negatively impact the organization, the leader could be tempted to not share the information. Unfortunately, there are all too many examples of alleged cover-ups in healthcare and academic medicine. The allegation of a cover-up may not be substantiated but it may be perceived as being the case. Regarding the public, perception is often the reality. The following examples compare cases where there might have been an opportunity for improved communication to those in which there was clear and transparent communication and disclosure. They demonstrate the difficulties in providing need to know communication versus full disclosure and the risk of a perceived cover-up.
ENSURING ETHICAL LEADERSHIP IN ACADEMIC MEDICINE

CASE EXAMPLE: Potential Opportunities for Improved Communication

In November 2018, the Centers for Medicare and Medicaid Services (CMS) issued a Statement of Deficiencies concerning the death of a patient at Vanderbilt University Medical Center (VUMC). The 56-page report included staff statements about medical errors and hospital staff conduct that constituted an alleged cover-up. The fatal incident occurred on December 26, 2017 when a 75-year-old patient was mistakenly given the drug vecuronium rather than Versed that was prescribed. Though the standard of care required monitoring for the prescribed medication Versed, no monitoring took place. The CMS report exposed nursing deficiencies along with hospital non-compliance with its own policies and procedures and local and state regulations.

CASE EXAMPLE: Potential Opportunities for Improved Communication

A second example is the alleged cover-up of by Seattle Children’s hospital of an aspergillus mold contamination that led to the infection and subsequent death of several children over time. The organizations involved with these two examples are leading academic health centers and known for high quality care and top tier educational and research programs. The allegations about a perceived cover-up have not been proven but likely created some communication challenges. The point is that this can happen to any academic medical center. The most effective leaders will be prepared to manage communication of these dicey issues. Having a communication team and potentially an external consultant in these matters is quite common in major academic organizations.

CASE EXAMPLE: Proactive Response and Communication

Fortunately, there are classic examples of how to effectively manage these instances from which we can learn. For example, the Tylenol poisonings in 1982 wherein Johnson & Johnson found itself in a precarious position. One of its leading products had killed seven people in a relatively small area. The response of Johnson & Johnson to the Tylenol Poisonings in 1982 has received accolades as an example of how leaders should respond to a crisis impacting the public. The company had never established a permanent public relations department other than an advertising and marketing division. Johnson & Johnson made several key decisions in response to this crisis. On October 5, 1982, seven days after the first reported death, Johnson & Johnson issued a nationwide recall of all Tylenol Extra Strength capsules. This included over 31 million bottles at an estimated retail value of over $100 million. Their market share collapsed practically overnight from 35% down to 8%. By making this decision, Johnson & Johnson showed that they were not willing to take any risks with the public’s safety, even if it cost them millions of dollars. These incidents led to reforms in the packaging of over-the-counter medications and to federal anti-tampering laws. The actions of Johnson & Johnson to reduce deaths and warn the public of poisoning risks have been lauded as an exemplary public relations response to such a crisis.

CASE EXAMPLE: Proactive Response and Communication

A second example occurred in December of 2004. An error by elevator workers occurred at Duke Health Raleigh Hospital and Durham Regional Hospital. They had inadvertently drained hydraulic fluid into empty soap containers and capped them without changing the labels. This resulted in contamination of the sterilization process for surgical instruments and an institutional crisis. Within hours of learning of the event the chancellor for health affairs, Dr. Victor Dzau, assembled a crisis team. Dzau and his team made patient safety the primary and to take action to assure the sterilization process had not been compromised. The next priority was to communicate an accurate message to the patients and public while avoiding unnecessary anxiety or confusion. In both instances, thoughtful leaders responded effectively and in a timely and transparent manner keeping the best interest of the public and patients the top priority.
Management of Information

The case examples indicate that concise and timely communication concerning major events in an organization is paramount. It is critical to have a professional communication team that can help frame and prepare the message. However, it is the leader’s responsibility to deliver the message. Further, the decision to release the information about a major event, good or bad, is the responsibility of the leadership team. The ethical principle guiding information disclosure is doing what is best for society. What should the timing be? Is it better to release the news ASAP or wait until the result is proven and durable? How and when does one communicate a terrible occurrence within your organization? Although each circumstance will be unique, the underlying principle is timely, open and transparent communication.

According to Johnson, unethical leaders have several deviant behaviors relative to information: they “deny knowledge of the information they possess, hide the truth, fail to reveal conflicts of interest, withhold information that followers need, use information solely for personal gain, violate the privacy rights of followers, release information to the incorrect people, and prevent followers from releasing information that they are ethically bound to release.”

In each of the major leadership domains, there can and will be examples of delivering information, both good and bad, about your organization. For the leader having a communication team is critical to delivering the right information at the right time.

Consistent Decision-Making

Definition

Leaders, whether in business or medicine, are human and are prone to develop closer relations with some of her or his colleagues or subordinates than others. These may be people that the leader hired, people who are part of the leadership group, or people that share common interests such as the arts, golf, or perhaps their children go to the same school. Whatever the reason, there could be a tendency for the leader to treat this group of people more favorably than others. It behooves the leader to be cognizant that such relationships could lead to inconsistent decision-making. This so called “in-group” may have higher levels of trust or belong to the same clinical department or product line and share in the financial rewards of decisions that may favorably affect that unit. The “out-group” may not be as aligned with the leader. The relationships are not as supportive or trustworthy. When this group seeks access to resources, the leader, who is unaware of the obligation to be consistent and fair, may respond in the negative as opposed to how the same request from the “in-group” is responded to.

Achieving Consistent Decision-Making

A challenge for the leader, surgical or otherwise, is to be aware of these natural tendencies and try to control them in order to maintain consistent and equitable decision-making. In some instances, it is helpful to develop defined decision-making processes with use of arm’s length third-party committees to distribute organizational assets such as capital or space (office, research, or clinical). Proponents of leader-member exchange theory encourage leaders to develop closer relationships with as many of an organization’s followers as possible including faculty, physicians, and other professional staff. The process of engaging the organization may involve daily walk rounds, video blogs, and town hall meetings. Most effective is meeting as many people one on one as possible. In some large institutions, this may be difficult and assigning some of this to the leadership team can help. Remember there is no substitute for a handshake and a conversation no matter how short the duration.
Loyalty

Definition

The effective and ethical leader is loyal to her or his organization, customers, and followers and expects the leadership team and followers to be loyal and upfront as well. Customers in health care can include patients, students, residents, and fellows in training. Followers include physicians, nursing staff, OR personnel, and other health system and department employees. In addition, the leader must be true to the governing board and loyal to their interest. The obligations may extend to larger organizations such as a university or college or hospital system as well as the community in which the organization is located. In addition, the leader must be loyal to the followers as noted above.

Management of Competing Loyalties

Tension and friction not infrequently develop between the leader’s fiduciary responsibility and organizational loyalty and loyalty to the employees and patients. During times of financial stress and lower operating margins, leaders and boards tend to focus on the bottom line. Reductions in staff are usually considered. Yet, a primary responsibility of a leader is to look out for those in their charge. This is a competing loyalty to financial responsibility. Hence, leaders must balance their responsibilities such as trying to find practical solutions to financial downturns that can protect the employees. These may include furloughs that usually retain benefits or broader reductions in pay with greater reductions among leaders than regular workers. These were all used in various permutations by a number of institutions during the COVID-19 pandemic.

In addition, leaders must appreciate the impact of staff reduction on patients. Efforts to control expenses by reductions in staff and layoffs is a particularly challenging issue for patient care which may be negatively impacted by higher patient-to-nurse ratios. Reductions in OR staff can reduce the number of operating room suites which are available daily and access to timely surgery. Reductions in the ED can impact the number of patients seen, decrease the timeliness in which a patient may be seen and increase the hours on diversion hence impacting the entire loco-regional emergency medicine delivery system. Further, the reduction in patient-staff ratios in ambulatory sites can lead to safety and quality issues and fewer patients being seen. Hence workforce cuts while helping the bottom line through expense reduction can lead to quality and access issues for patients and concerns for patient safety.

The leader needs to have a balanced response in financial downturns and clearly communicate her or his concerns and plans to the staff. Although layoffs may be necessary, less consequential options for the employees should be sought as noted above. Alternatively, this might include other forms of expense reduction, including enhanced efficiency measures and focus on revenue cycle management. In addition, most organizations have a backlog of new hires that are pending. Prior to pursuing widespread workforce cuts, leaders could consider a hiring freeze. Every new position not filled saves a layoff and protects the livelihood of your employees. The key to loyal management is balancing one’s responsibilities and identifying novel solutions combined with free and transparent communication to all stakeholders. Leading during a crisis requires swift decision-making but also increased sensitivity to the needs of staff and faculty. During the COVID-19 pandemic there were examples of excellent hospital administration efforts and performance as well as some debacles.
Healthcare organizations including AHCs faced many challenges as the Covid-19 pandemic. All were in a precarious situation exacerbated by the risk of infection of their health care providers and learners involved in the direct delivery of care to Covid-19 patients. Several leadership principles emerged through effective management the crisis.12

**Accelerating Decision-Making**
A major challenge of AHCs in times of crisis is their deliberate decision-making processes designed to create consensus. During a crisis, these same processes can slow action. In a crisis, a leader must change to operating the AHC with actions taken at “war-room” speed. This involves power consolidation amongst a few leaders while maintaining input from diverse stakeholders and most importantly making swift real-time decisions. Early on in the Covid-19 pandemic, many AHCs struggled with the balance between “prevention of harm” by minimizing workforce and patient exposure and maintaining access and availability of all services. Effective leaders consolidated decision-making and developed a united vision, strategy and action plan.

**Putting People First**
Institutions that continued business as usual without appropriate personal protective equipment (PPE) dramatically eroded trust between front-line staff and leadership. Contrarily, AHCs that stopped non-essential care including elective surgery and procedures were able to protect the staff with PPE. This sent the message that to the staff that leadership was concerned for them and their physical safety. During this crisis, the most effective leaders acknowledged if appropriate PPE could not be obtained and were forthcoming about what they were doing to solve this problem. To be clear, there is no faster way to destroy employee morale than to operate a workplace that is dangerous to the workforce without visible, determined leadership addressing that danger. Effective leaders were also sensitive to the emotional health issues of health care providers, staff, and learners. The pandemic created untenable situations involving an incurable and unpredictable disease with a high mortality rate. This was worsened by the fact that care was rendered to dying patients during a time when family members were not allowed to visit and support their loved ones. In addition, many health care workers were concerned and frankly scared that they could spread the infection to their families. Loss of human life was immense intensifying the stress of the situation. Best practices included providing 24/7 support for employees and other stakeholders by retaining specialized therapists, chaplains, and psychiatrists.

**Be Visible and Express Gratitude**
During the Covid-19 crisis the best leaders were visible. Healthcare workers on the front lines greatly benefited from seeing managers and leaders from across the organization in person. There were few public examples where leaders led the Covid-19 response remotely and these invariably resulted in poor morale. Recognition of the work and commitment of the staff proved to be of added value in sustaining morale. Simple acts such as the provision of more accessible free parking and free meals enhanced morale.
Making Personal Sacrifices to Build Morale and Trust

The pandemic necessitated decreases in surgical volume, outpatient visits and diagnostic testing in order to have sufficient hospital beds and PPE for the care of patients infected with COVID-19. The resulting financial losses will impact the economic stability of healthcare for some time to come. The bottom-lines of many hospitals and physician practices including those in AHCs were drastically reduced. Physicians took salary cuts, and some were furloughed. Coming out of the pandemic there may be an impact on employees’ compensation and time off as hospitals plan to take care of the backlog. In the future this may impact the compensation of physicians and staff, and associated with Covid-19, it is paramount that the leadership make visible personal sacrifices to demonstrate their personal alignment with the tough financial decision they are making; clearly shared sacrifice at least demonstrates that the burden is equitably spread. For example, it was reported that executives at Denver Health received bonuses during the pandemic ranging from $50,000 to $230,000 as some physicians and other health care personnel who were not on the front lines were furloughed. This was catastrophic for morale. Other institutions took a different approach. For example, Kevin Tabb, Chief Executive of Boston-based Beth Israel Lahey Health, took a 50% pay cut along with a 20% cut for other members of his executive team. John Fox, the CEO of Michigan’s Beaumont Health System, took a 70% base pay cut and he implemented layoffs of administrative staff not directly involved with patient care. During this crisis, sacrifices such as these earned the staff’s respect; bolstering the morale and their trust in the organization.

The leader also has an obligation to be loyal to patients. Decisions regarding organizational management and fiscal responsibility must be balanced by the needs of the patients. This is noted above in the staffing needs to maintain patient access and quality. Equally important is the need to deploy capital to keep up the infrastructure of the organization. If the facilities deteriorate, it may impact the quality of care as well as education and research programs and patient confidence in the health-care organization. It seems reasonable that if an organization or department is having financial difficulties, the leadership team may need to cut back on capital expenditures to maintain the bottom line and maintain payroll. These decisions could be weighed against the impacts of lack of capital investment. If capital investments are being curtailed to maintain a bonus pool for senior executives or physicians or to build increased reserves, the decision may need to be reconsidered in that the negative impact may far exceed the perceived gains. Navigating these tensions between performance, personal gain, ethical obligation, and duty are at the heart of ethical leadership.

CASE EXAMPLE: Competing Loyalties

An example of competing loyalties is the decision to close Philadelphia’s Hahnemann University Hospital on July 26, 2019. For decades, the hospital had been struggling financially and then in January 2018 it was purchased by the American Academic Health System, a for-profit corporation. There was hope for a turnaround but apparently the for-profit nature of the owner and the safety net priorities of the hospital were not compatible. A decision was made to close the hospital. The closure left some 2572 people without jobs and orphaning 570 residents and fellows. To make matters worse, the shutdown was precipitous, occurring within four weeks. There was inadequate communication from the administration leaving the staff and trainees to turn to local news for information. The competing loyalties involved were the corporate bottom line, the followers, and the public. This was a safety net hospital and the primary teaching hospital for Drexel University College of Medicine. This example also demonstrates a real need for a leader to recognize competing loyalties and employ ethical decision-making when finding equipoise. Furthermore, this is an example of poor information management. It is essential for a leadership team to have clear communication concerning dramatic organizational change.
Responsibility

Definition and Scope

A leader has a complex array of responsibilities that can be defined as personal, organizational and societal. Faculty, hospital, and departmental staff are responsible for their actions within the scope of their assignments. On the other hand, depending on the specific role, leaders have a much broader scope of responsibility for performance of entire units including the department, service line, and health system. The leader has organizational responsibility. The leader is held accountable for the performance of these units as well as the individual actions of followers as prescribed by the code of conduct or human resource requirements and rules. In addition, the leader also has a societal responsibility to the customers and patients. With leadership comes great responsibility and accountability. How far the accountability reaches may depend on the specific situation.

Managing Responsibility

Faculty and Staff

A responsible leader makes reasonable efforts to prevent unacceptable employee-employee interactions and unethical behavior. Many of these occurrences are guided by institutional policies. For example, do you think a chair of surgery is accountable for unprofessional conduct of a physician on the trauma service? In this circumstance the scope of accountability is very broad. It is probably unreasonable to believe that the chair is personally responsible for the unprofessional interaction, but he or she is responsible to the organization to be certain the faculty is aware of institutional policies guiding employee interactions and that appropriate corrective measures are taken to avoid future instances.

Scientific Misconduct

Another example is when a faculty member publishes falsified scientific data. Is the chair or dean personally accountable for this occurrence? Many would argue no and some yes. However, the leader has an obligation to the organization and the scientific community to establish and maintain a culture of research integrity. This means having educational and compliance programs in place to ensure that faculty are aware of the personal ethical obligations for performing research. The individual faculty member is responsible for his or her actions.

Contrarily, if the leader is aware of professional misconduct or research misconduct and takes no corrective action, then he or she is accountable for not meeting the obligations set forth by the organization. The leader is responsible for her or his actions or inaction set forth in the organizational policies and procedures.

Medicare Fraud

Medicare fraud and billing practices is another area falling under the leader’s responsibility. The leader is responsible for ensuring that compliance programs are in place, that physician billing activity is monitored and reviewed, and that corrective action plans are in place and used to intervene on individual physician billing practices. It follows that he or she is therefore accountable to the organization if there are lapses in such programs. Yet, the leader may have little or no accountability for an individual physician’s non-compliance. However, should the leader not act when a physician is non-compliant, particularly after repeated infractions, then it is possible, that the leader could share in the corrective steps for such actions.

Credentialing

The leader has a responsibility to patients to assure them a safe environment, with competent physicians and nursing staff. It is essential that the ethical leader abide by the medical staff bylaws and organizational policies concerning credentialing. The wise leader will defer final recommendations concerning privileges and credentialing to the physician leadership of the medical staff. To act alone is unwise and fraught with personal risk.
Summary

The ethical challenge for a physician leader is to find equipoise in managing the tension created between and within the burdens of leadership defined by the six ethical burdens described by Johnson: Power, Privilege, Information Management, Consistency, Loyalty and Responsibility. The complexity of resolution will vary between situations and the impact on the organization and various stakeholders including: the employees, faculty, learners, and the public. Achieving successful resolution occurs with the leader practicing ethical decision-making.

References

Establishing an Ethical Culture: The Importance of Ethical Decision-Making

KEY POINTS

• Fairness in the management of the tensions created by the dynamic relationship between the leader and his or her followers yields a successful unit by all measures and an engaged and satisfied group of faculty and staff.

• Aligning individual faculty expectations with organizational goals is an essential priority for an effective leader.

• Management of academic units is enhanced by establishing and promoting an ethical culture which may include establishing a code of conduct.

• Ethical decision-making strengthens an ethical culture in the organization:
  – The search for guidance in ethical decision-making for the physician leader should be an ongoing one.
  – There is no absolute roadmap of how to make ethical decisions nor is there a flow chart to clearly identify how to avoid making decisions that may not meet the ethical expectations of others.
  – A framework for making ethical decisions should not be thought of as a full-blown ethical theory, but rather as a means of using multiple ethical theories and ethical principles along with additional considerations in deciding what is the optimal choice.
  – Ethical decision-making is important for all decisions rather than only for those that narrowly fit within a specific category.
CHAPTER FIVE: Establishing an Ethical Culture: The Importance of Ethical Decision-Making

The Leader’s Role in Managing Ethical Issues

How might a leader best address ethical issues that arise in the course of management? The ethical challenges of leadership are the use of power, privilege, management of Information, consistent decision-making, loyalty and responsibility. These come into play as the leader oversees the major domains of leadership including: 1) faculty and staff, 2) education of medical and postdoctoral, students, residents, and fellows, 3) research in basic science, clinical trials and health services, 4) clinical care and 5) finance. The interface created by the dynamic relationship between the leader and his or her followers may create tensions that may be difficult to navigate. Ensuring an ethical culture, applying ethical decision-making and stressing fairness will enhance management and lead to a successful unit and an engaged and satisfied group of faculty and staff. Contrarily, failure in achieving these principles can lead to a unit that does not meet organizational expectations and a faculty and staff who are disengaged and dissatisfied potentially leading to premature attrition or increasing conflict and discord. Strategies that may facilitate the management of ethical issues include aligning faculty and organizational priorities and establishing an ethical culture.

Alignment of Organizational and Faculty Priorities

Aligning individual faculty expectations with organizational ambitions is an essential management priority for the effective leader. Both faculty and staff have expectations that include access to the resources to do their work, the opportunity for promotion, a safe working environment, and financial security. Not surprisingly each will also have his or her own goals and ambitions that will catalyze the interaction between the follower and the leader. From the leader’s perspective, he or she has the power and responsibility to provide for the followers but also has a loyalty to the institution to meet expectations in the tripartite missions. Leaders may also have personal ambitions that come into play as well and these must be modulated and prioritized so as not to interfere with the fair and successful management of the unit.

In the end, the outcome of these interactions is related to the fairness of the leader’s management of resources and opportunities, which in turn influences promotion and compensation. Examples of resources include start-up packages, research and office space, protected time, access to clinic space and the operating room; examples of opportunities include assignment to intra-unit or extra-unit leadership positions. Fairness encompasses the ethical challenges of both the transparent management of information and consistent decision-making. Faculty and staff have a right to know the status of the unit in meeting organizational goals as well as to understand how resources are allocated. Further, they expect that decisions will be made in a consistent manner without favoritism and bias.

Clear communication processes that engage faculty and staff are essential to satisfy both followers and organizational leadership. Fairness is achieved by establishing transparent unit goal setting and creation of easy to understand formulas for allocation of resources including compensation, protected time, space and promotion as well as clear processes by which faculty may volunteer or apply for internal or external leadership roles.

Promoting an Ethical Culture in Academic Health Centers

Management of academic units is enhanced by establishing and promoting an ethical culture. In addition, in these high performing organizations, leadership proactively anticipates the types of ethical challenges an organization may experience and a process for managing potential ethical breaches. Ensuring an ethical culture is more likely if the leader has a virtuous character, knows her or his duties and adheres to their personal values when navigating the complex social, financial, and regulatory environment of academic healthcare. Being self-reliant and confident in one’s purpose and duty is crucial, but alone, this is insufficient. The leader must first connect with the members of the organization, including the faculty, staff, and learners, in order to establish and maintain a trustworthy, fair, and just culture that characterizes a strong ethical organization. Secondly, it behooves the leader to consider ethical dimensions and how they interface with one’s institutional responsibilities. Academic medical leaders are often presented with situations that require them to consider several ethical dimensions prior to a decision. In these situations, an apparently innocuous decision concerning an unrecognized ethical breach may turn into a very dicey ethical issue. Ethical decision-making is an essential leadership skill and necessary for ensuring an ethical culture.
To establish an ethical culture and better manage potential ethical issues, it is recommended that the leader in academic medicine consider five best practices (see Table 5-1). These include an ethical risk assessment, developing written standards that define an organization’s code of conduct and systems of accountability, building a culture of integrity, promoting organizational values, continual reappraisal of the ethical foundation of an organization and initiation of continuous improvement. The ethical nature of an organization can be measured. This is a common practice in business. Borrowing from business and industry we have identified the ten key drivers of an ethical culture academic medicine which are shown in Figure 5-1.

**TABLE 5-1: Key Steps to Establish an Ethical Culture**

1. Honestly assessing the existing strengths and weaknesses and available resources through an ethical risk assessment which should also include exploring future vulnerabilities
2. Establishing a strong foundation by developing written standards of ethical workplace conduct, systems of accountability and developing and providing ongoing support for organizational ethics and compliance programs
3. Building a culture of integrity from the top down by modeling ethical behavior and keeping promises and honoring commitments
4. Focusing on organizational values and communicating them in policy development, reward systems, performance evaluation and promotion decisions
5. Re-evaluating and revising the programs based on an assessment of what is working and what is not as well as identifying what new vulnerabilities may have emerged

**FIGURE 5-1:** Ten drivers of an ethical culture academic medicine. (Adapted from the Ethical Culture Healthcheck Good Corporation Ltd. [https://www.goodcorporation.com/services/measuring-corporate-culture/](https://www.goodcorporation.com/services/measuring-corporate-culture/). Accessed June 30, 2020.)
An organization with a strong ethical culture has values and standards that are clearly defined, published, and understood by most of its members. It has been shown that an organization's ethical climate can improve employee morale, institutional and unit commitment and retention of faculty and staff. One of the important priorities of the academic physician leader is to establish the ethical standards as it relates to carrying out the missions of the unit or organization and provide and communicate a framework for members to make the right decisions and consequences for non-compliance. In some organizations this takes the form of a code of conduct. Examples include that from the Jacobs School of Medicine at the University of Buffalo and Johns Hopkins Medicine.\textsuperscript{2,3}

To achieve an ethical culture the leader needs to be a role model and visible. The faculty and staff look to you and your management team to model acceptable behavior in the workplace. If top management fails to model ethical behaviors, then a code of ethics is worthless. Further ethical expectations must be communicated with visible rewards for ethical behavior and negative consequences for unethical ones.

Ethical breaches may occur in any academic health center. Bad apples may exist in any organization and may be involved in unethical behavior. However, such behavior may go undetected unless there is a system of anonymous reporting. Optimally, organizations provide mechanisms for faculty and staff to report unethical behavior in a confidential manner, in order to detect a “bad apple” and prevent ethical breaches on a large scale. These anonymous reporting systems or ethics hotlines have evolved as a best practice. Ethics hotlines demonstrate the commitment of leadership to organizational ethics. By using such systems, organizations, including those in healthcare, can better detect specific ethical breaches including financial irregularities, privacy and security issues, issues involving workplace safety, ethical and compliance violations, and human resource issues including: drug and alcohol abuse, misconduct, insubordination, discrimination, harassment, aggressive behavior and hostile work environments, abuse of authority, retaliation and attendance policy violations. A reporting hotline can eliminate confidentiality concerns by providing the employee the opportunity to submit a report outside of the workplace. The employee must have access to the reporting hotline 24 hours a day, seven days a week, meaning a report can easily be filed outside of normal working hours. In addition to a toll-free hotline, the employee should be able to submit a report via alternative methods including email or web-based systems. These have become the preferred methods of submitting complaints. Using fraud as an example, the 2016 Association of Certified Fraud Examiners (ACFE) survey indicates that, by far, the most common way organizations detect fraud is through anonymous tips received via ethics hotlines. According to the survey, 43.5% of frauds in U.S. organizations with 100 or more employees were discovered through tips on an ethics hotline, while only 18.6% were uncovered by internal audit and 12.7% by management review. Use of anonymous reporting systems can promote a more transparent ethical culture.\textsuperscript{4}

Although institutions with highly functioning ethical cultures, may be susceptible to ethical breaches, there is evidence that establishing an ethical culture may help reduce the occurrence of these deviations in an organization. Alison Taylor wrote in the Harvard Business Review “5 Signs Your Organization Might Be Headed for an Ethics Scandal” in which she describes the difference between ethical and unethical culture.\textsuperscript{5} She pointed out that ethical cultures tend to be unique and are not the same. Whereas unethical cultures tend to be similar and allow conditions in which unethical behavior may flourish. She reasons that ethical breaches cannot always be explained on the “bad apple” theory and that sometimes the orchard as well as the tree are bad. As examples, she cites that individuals alone cannot fully explain what transpired at Wells Fargo\textsuperscript{6} to create a culture of corporate fraud or Volkswagen’s unbridled ambition to top the global auto industry promising high mileage low emissions high performance diesel engines that resulted in installation of software that cheated emission tests in 11 million diesel cars.\textsuperscript{7}

She described her research as a “study which complemented a review of the literature on this topic by querying 23 integrity experts concerning to behaviors common to unethical companies”.\textsuperscript{5} Their answers fell into a clear pattern of five characteristic organization traits that were correlated with ethical scandals, as quoted from her article.\textsuperscript{5}

1. “Urgency and fear: Following corruption scandals, leaders tend to describe events in terms of pressure, necessity, and what the company needed to do to survive.”
2. “Isolation: Groups and teams that are far from headquarters—either in geography, access to information, or both—are vulnerable.”
3. “Fragmentation and plausible deniability: Organizational complexity, matrixed responsibility, and a lack of clarity as to roles can help feed and justify conditions in which each decision is judged in isolation, and no one is held broadly accountable.”

4. “Success and impunity: A tendency not to question success. When a team markedly outperforms its peers, it develops a mystique that serves to block scrutiny of the basis of that success.”

5. “In-group language: Humans need both to hide and rationalize unethical behavior, leading to the widespread use of in-group jokes and euphemisms”. These obfuscate illegal activity.”

It is possible that such characteristics may play a role in organizational ethical breaches in academic medicine as well. These tendencies may possibly be countered by establishing an ethical culture. Furthermore, establishing an ethical culture will be more successful if the leader makes use of ethical decision-making.

**Ethical Decision-Making**

Ethical decision-making is probably the most important skill for the leader to master. Ethical decision-making is an active cognitive process for the prevention and/or resolution of ethical conflicts. It involves logic and reason as well as intuition and emotion. Johnson observed that ethical decision-making requires a unique framework consisting of moral imagination, identification, evaluation, integration, and obligation. Shamoo and Resnik describe a practical method to approach ethical decision-making consisting of: problem definition, information gathering, exploration of viable options, application of ethical principles or policies to the options, resolution of discordance between ethical principles and policies or rules, and finally making a decision and taking action.

Development of specific guidelines for ethical decision-making by physician leaders is an iterative process undergoing continuous reassessment and improvement. There is no absolute roadmap of how to make ethical decisions. Unfortunately, there is also no flow chart to clearly identify how to avoid making unethical decisions. Ethics is neither defined by the law nor completely encompassed by cultural norms even though both considerations are important for making ethical decisions. Inevitably, the close analysis of ethical decision-making can seem overly technical and divorced from the reality of the social context and interpersonal relationships in which ethical decisions must be made. However, the benefit of considering the steps in ethical decision-making is in creating a series of important considerations that the physician leader can attend to no matter how complex the situation.

A framework for making ethical decisions should not be thought of as a full-blown ethical theory, but rather as a means of using multiple ethical theories and ethical principles along with additional considerations in deciding what the optimal choice is. For example, the theory of utilitarianism (the greatest good for the greatest number) cannot be applied in all circumstances. There will be situations in which considerations of justice or fairness will take precedence over making the largest number of people happy. Thus, it is best to think of particular ethical theories as frameworks that will play a greater or lesser role depending on the situation.

Although many considerations of ethical decision-making begin with the attempt to define what the ethical question is, we believe it is more helpful to conceptualize ethical decision-making as important for all decision-making rather than only for those that narrowly fit within a specific category. If the leader thinks of making every decision in an ethical fashion, then the necessity of defining which decisions are ethical ones and which are not will disappear. It is also important for the physician leader to realize that in his or her position as a role model, there will be many situations in which the actual decision made will be less important than the method that was used in making the decision. A thoughtful, deliberate approach that takes into consideration multiple perspectives will be far more valuable than an authoritarian jump to a position even if the same decision is ultimately made.
Shamoo and Resnick suggest a series of considerations that can helpfully guide ethical decision-making. It begins with defining the problem at hand. Sometimes, there are several problems, but carefully understanding the central problem is critical. Second, gathering the information about the problem is necessary. For example, as consideration the medical facts is essential in a challenging clinical case so is understanding the facts concerning the difficult problem requiring resolution. Also important is the appreciation of whom are the stakeholders involved in the problem requiring a decision. Third, is consideration of what the various options are and whether they are practical options or simply theoretical options only. Fourth, is the consideration of how the various options relate to different ethical principles or ethical theories. Fifth, once a decision is made should be made it should be communicated to the stakeholders. Finally, the outcome of the decision should be carefully tracked and reflected upon so that future decisions can be informed by what was learned from the prior decisions.

By way of illustration, we will outline possible approaches to making ethical decisions that may be helpful in deciding how to manage challenging circumstances. We will use a fictitious example showing the importance of non-maleficence and justice. In addition, we will cite an example of organization ethical leadership during the COVID-19 pandemic.

CASE EXAMPLE: Credentialing New Procedures (Fictitious)

Consider the case of a section chief (Dr. Smith) who is asked by one of the surgeons in the group (Dr. Jones) to increase the necessary experience before approving credentials for a novel laparoscopic approach to bariatric surgery. In this scenario, Dr. Smith is being asked to change the credentialing requirements so that future new surgeons will likely not be able to get privileges to do the laparoscopic procedure right out of training. The problem is that such a change will give Dr. Jones a competitive advantage over other new surgeons who will not be allowed to do the new procedure until they have additional training. Certainly, Dr. Jones is an interested party, but future new surgeons hired into the section will also be affected. In addition, it is the patients who will ultimately benefit from better-trained surgeons doing the procedure or will potentially be harmed if there are fewer surgeons available who have credentials to perform the procedure. Among the important ethical principles that must be considered are beneficence (that is, doing good for patients) and nonmaleficence (avoiding harming patients). In addition, the importance of justice (treating people fairly) is also an important consideration.

How new credentialing requirements will affect patients is dependent on whether such requirements will reasonably be predicted to improve the outcomes of patients or simply create barriers to patients being cared for in an expeditious manner. A consideration of the options open to Dr. Smith is important. Can the credentialing requirements really be changed, or will this require a new medical staff policy? If a surgeon joins the staff without meeting the training requirements to do the new laparoscopic procedure, will there be a mechanism to gain such experience without taking unreasonable time away from one’s practice? Answers to these questions will help define some of the practical options that are available to Dr. Smith. If, after reviewing the data about the new procedure, Dr. Smith believes that it is a novel and complex procedure that warrants more training in order to be safely offered to patients, then the requirements to obtain privileges for the new procedure should be made more stringent. This decision will improve the safety of patients and this should be communicated along with the decision that is reached. In the name of fairness, Dr. Smith might also point out how other surgeons can obtain the experience needed to safely qualify for the privileges. Finally, the outcomes of the decision should be tracked to determine what outcomes patients must ensure that the privileging standard need not be changed in the future.
CASE EXAMPLE: Organizational Ethical Decision-Making

As most hospitals in the United States debated the Ethics of reducing non-urgent surgical procedures in order to increase the number of hospital beds that were anticipated for COVID-19 patients, the American College of Surgeons (ACS) under the leadership of Dr. David B. Hoyt took up this challenge. At local hospitals there were disagreements about the definition of urgent and elective surgery, who should make the decision to cancel a case, and how long could they be postponed. Dr. Hoyt working with the Regents and Officers of the ACS developed multiple guidelines concerning COVID-19. As an example, a statement was published on the Web on March 13, 2020 concerning recommendations for management of elective surgical procedure and then developed national guidelines for the triage of non-emergent procedures.10

In addition, they used their existing communication vehicle, the ACS Bulletin, to provide updates to surgeons twice weekly. The bulletin for March 24, 2020 is in the attached link. In addition, to multiple specific guidelines they reiterated the guidelines for triaging non-emergent procedures and expanded upon them by suggesting “A Surgical Review Committee, composed of surgery, anesthesiology, and nursing personnel is essential to provide defined, transparent, and responsive oversight. This committee can lead the development and implementation of guidelines that are fair, transparent, and equitable for the hospital or system in consideration of rapidly evolving local and regional issues.”11

Dr. David Hoyt, Executive Director of the American College of Surgeons, further elucidated the commitment of the ACS and core guiding principles in an ACS Communities post quoted below which exemplify some of the key elements of ethics and the management of crisis situations and ethical decision-making at the organizational level.

“We’re all going to be called on to be leaders during this time, and it’s a natural function that surgeons do with ease. In his book The Art of War, Sun Tzu talks about being a strategic leader. The principle is to know yourself, take care of yourself, and know your enemy, though in Chinese it actually means know the “other”. First, we are committed to being present, and communicating totally, frequently and truthfully. Secondly, we embrace the principle that core leadership during a crisis must exercise pragmatic optimism and empower those around us to help. It’s also important to generate support from our constituencies and manage our relationships both with them and superiors. Finally, we all have a responsibility to continue to fight the magnitude of this crisis and maintain resilience and patience. To that end, develop a plan, be strategic, and follow it.” Dr. David B. Hoyt, March 21, 2020 17:23.12,13

In addition, the ACS as an organization was sensitive to the ethical challenges created by the pandemic. In the ACS Newsletter of March 24, 2020, the ACS Committee on Ethics prepared guiding principles to help surgeons and their institutions in the decision-making process. They examined the ethical issues caused by the triaging challenges, moral distress, and financial burden created by the Corona/COVID-19 global pandemic. “Most physicians who have been educated and practice in well-resourced environments are used to making decisions based on what is best for each individual patient. This patient-centered ethics approach pays great attention to the principles of beneficence (taking steps to benefit patients) and respect for the autonomous choices of individual patients. Surgeons, who can only operate on one patient at a time, are particularly focused on patient-centered ethics. We now increasingly are being forced to shift to a public health ethics model. It is no longer a matter of what will be best for each individual patient, but rather, what is best for the group.”13
In this example, Dr. Hoyt and the ACS Leadership demonstrated many of the key attributes and steps in ethical decision-making:

- An ethical problem was identified: Acuity of COVID-19, the severity of the illness and the need for hospital beds and ICU beds and ventilators as well as the needs of the patient having non-urgent surgery
- Cognitive and emotional dimensions were considered as it was a dual process involving both logic and emotion
- Moral Sensitivity to the issues was clearly expressed in the statement of the ethics committee.
- Moral judgement and recommendations were made (what is the right or wrong thing to do in this situation: you cannot cancel all the surgeries and you cannot cancel none of them)
- Avoidance of ethical blind spots such as group favoritism and implicit prejudice
- Moral focus to follow through
- Moral character as evidenced by recognition of duty

Summary

Although there is no single perfect method of making ethical decisions, the considerations noted above provide a framework for the surgical leader to thoughtfully consider what may be difficult choices. By being deliberate and thoughtful in taking into consideration the issues noted above, the physician leader will not only have a greater chance of making good decisions but will also model the type of ethical decision-making that all surgeons should utilize in their practices. Ethical decision-making is the primary foundational element of an ethical culture.

References


KEY POINTS

• No matter how mature and effective the ethical leadership and culture of your organization, there will always be the risk of ethical breaches by individuals in the midst of an organization. They will never be eliminated.

• Ethical breaches may involve clinical care, billing compliance, personnel interactions, academic integrity, research, and education.

• Although the number of severe disciplinary actions involving physicians is low averaging about 1/1000 physicians, it is similar to the annual incidence of breast cancer and far greater than the incidence of HIV.

• Despite clear patterns, no factors provide readily observable red flags, making prevention of ethical breaches difficult.

• It behooves the leader and her or his organization to prepare and to have a system in place to recognize and manage incidents involving ethical issues in a timely fashion and with full transparency.

• Administrative inaction can be viewed as breaking our social contract with the public and our internal community.
Introduction

It seems that corporate scandals and moral lapses occur daily in a variety of sectors from business to organized religion. Healthcare and academic medicine are not immune from these egregious events. No matter how mature and effective the ethical leadership and culture of your organization, there will always be the risk of breaches by single individuals who disregard those principles. They will never be eliminated, and they must be managed.

Those we serve; the broader public, patients, faculty, staff, and learners; set high expectations for leaders to be the moral fiduciary of academic medical institutions. Leaders will be scrutinized and assessed on their ability to establish an ethical consciousness for the organization. We are expected to be the source of ethical guidance for all members of an organization as well as patients and other stakeholders. Rarely, ethical breaches will occur. These must be managed in a timely and transparent manner or risk loss of this trust.

Domains of Ethical Breaches

Academic physicians and surgeons have three major missions: providing care to patients, educating and mentoring students and residents, fellows, and colleagues, and advancing medical and surgical knowledge through research and innovation. Further, they have a responsibility to their institution as well as the societal priorities of their profession. Ethical issues may arise in any of the tripartite mission areas and in the potential conflict between professional responsibilities within and outside one's institution. As an example, the interplay between education and patient care can create situations in which the academic physician can be faced with dilemmas such as allowing trainees to perform some aspects of care and how much autonomy they should be given. By the same token, academic physicians are expected to conduct research and publish original articles reporting the results of their research. Maintaining research integrity is essential including as other issues such as authorship, courtesy authorship, plagiarism, and duplicate publication. In addition, conflicts of interest and conflicts of commitment may occur. Conflicts of interest (see Chapter 10) are more often discussed and processes for management are usually formally defined. Conflicts of Commitment (see Chapter 10) are not often discussed but are frequently observed through absences of academic physicians from their primary work in order to meet their obligations to present scientific work at academic meetings or engage in professional organizations with responsibilities outside of one's institution. Examples of such activity may include serving as an examiner or consultant for the board of certifying body or serving in a leadership role in an academic association.

Based on the above there are many areas in which the leader in academic medicine may face ethical issues. The most common include clinical care, research, human resources, and education. In each of these, misconduct of an individual employee, faculty member or learner may be the primary focus of the leader's intervention. However, concerns may also include lapses in performance of staff and faculty that lead to poor patient outcomes or violation of privacy rules (HIPAA), conflict of interest, or fraud and billing irregularities (upcoding), compliance issues, concomitant operations or procedures and lapses in research integrity.

Establishing an Ethical Culture

The prior chapter discussed the key steps in establishing an ethical culture. Although an organization with a strong ethical foundation and culture may have a lower incidence of ethical breaches, this may not be case. No matter how diligent an organization, there may be individuals, “bad apples”, who disregard ethical principles. Hence these unethical behaviors may never be completely eliminated. In order to police your organization, two steps are recommended. First, implementation of an anonymous and confidential reporting tool is necessary as discussed in Chapter 5. Secondly, appointment of a standing ethics committee or assignment of these responsibilities to an executive team in the medical staff office, department or college of medicine, human resources, or compliance.
**Frequency of Ethical Breaches in Academic Medicine**

It is difficult to estimate how often ethical violations occur in academic medicine. Yet, they do occur and likely more often than we would like to think. Dubois and colleagues reported a statistical and ethical analysis on 280 cases of serious ethical violations in medicine in the United States from 2008–2016.¹ The violations analyzed included sexual abuse, criminal prescribing of opioids, and unnecessary surgeries. The authors focused on these three violations as they were among the most common causes of major disciplinary actions and because they were more apt to directly harm patients, compared to upcoding or failures to disclose conflicts of interest. The findings showed some common themes. First, nearly all cases involved repeated instances (97%) of intentional wrongdoing (99%), by men (95%) in nonacademic medical settings (95%), with lack of adequate oversight (89%) and a selfish motive such as financial gain or sexual gratification (90%). More than half of cases involved a perpetrator with a suspected personality disorder or substance use disorder (51%). However, despite clear patterns, no factors provide readily observable red flags, making early detection and prevention difficult.

**State Medical Board Disciplinary Actions**

According to the Federation of State Medical Boards (FSMB), 0.5% of physicians are the subject of state medical board (SMB) disciplinary action each year, of which approximately 0.1% are severe actions involving revocation, suspension or surrender of their license.²⁻⁴ Dubois and colleagues point out that although the number of severe disciplinary actions is low, averaging about 1/1000 physicians per year, they remain urgent concerns.⁵⁻⁷ To put the annual incidence into perspective, they point out it is similar to the annual incidence of breast cancer and far greater than the incidence of HIV. Between 2003 and 2013, 2.9% of all National Practitioner Data Base licensure reports were for sexual misconduct. It is thought that this incidence is an underestimate as it relies on self-reporting. Only 5–10% of victims of physician sexual assault report it, which is lower than in sexual assaults in the general population.⁸⁻⁹

**Regulatory Compliance Issues**

Management of regulatory compliance issues is a major concern for health care leaders. These include potential Anti-Kickback Statute and Stark Law violations and fraudulent billing practices, cyber security breaches and HIPAA violations. The federal Anti-Kickback Statute is a health care fraud and abuse statute that prohibits the exchange of anything of value for referable services that are payable by a federal health care program. The Stark Statute makes it illegal for physicians to refer Medicaid and Medicare patients to any entity that he or she may have a financial relationship including ownership, investment interest, or other compensation arrangements. There are safe harbors for the Stark Statute including an Academic Medical Center exception.¹⁰ An example of a Medicare fraud case is the settlement in July 2012 by GlaxoSmithKline which paid a $3 Billion settlement for charges involving kickbacks and off-label marketing.¹¹ Investigations of privacy rule complaints are increasing. For example, according to US Department of Health and Human Services¹² there were 223,135 investigations for privacy rule complaints between April 2003 and November 2019. Of these 219,964 were resolved including 39,552 investigations with a finding of no violation in 12,058 (30%) and corrective action in 27,494 (70%). There were 3,171 complaints remaining open and 804 referrals to the Department of Justice. Most hospitals have adopted zero tolerance policies to privacy violations involving a patient's protected health information that can result in an employee's termination. An example occurred at Northwestern Memorial Hospital in March of 2019 where at least 50 employees were reportedly fired from Northwestern Memorial Hospital for accessing the medical profile and records of “Empire” actor Jussie Smollett without authorization.¹³
A violation of the Minimum Necessary Information Standard may be considered a matter for internal disciplinary action or termination depending on the circumstances and will depend on the policies in place at an organization and the severity of the violation. Leaders must initiate and oversee the investigation and act on the recommendations of the HIPAA Compliance Committee. A report from a HIPAA Journal post indicates that,

“Not all HIPAA violations are equal, although any violation of HIPAA Rules is a serious matter that warrants investigation and action by healthcare organizations. When a HIPAA violation is reported—by an employee, colleague or patient—healthcare organizations will investigate the incident and will attempt to determine whether HIPAA laws were violated, and if so, how the violation occurred, the implications for patients whose privacy has been violated, potential legal issues arising from the violation and possible action by regulators. Healthcare organizations will take action to ensure that similar violations are prevented in the future. Furthermore, when an employee is discovered to have knowingly or unknowingly violated HIPAA Rules there are likely to be repercussions for the individual concerned.”

The report went on to note that “an unintentional acquisition, access, or use of protected health information by a workforce member in which the acquisition, access, or use was made in good faith and within the scope of authority would not be a reportable breach and may not necessarily result in disciplinary action”.14

**Academic Integrity**

Issues of academic integrity are difficult to quantify. They include falsification of research data, duplicate publication and plagiarism as well as issues of conflicts of interest related to the pharmaceutical or technology industry. There is no doubt that current academic leaders will face such occurrences and potentially more so in the future. A pooled weighted average of 1.97% of scientists admitted having fabricated, falsified, or modified data or results at least once and 33.7% admitted other questionable research practices.15–17 Further, scientific misconduct is the leading cause of retractions. A detailed review of all 2,047 biomedical and life science research articles indexed by Pub Med as retracted on May 3, 2012 showed that 21.3% were attributable to errors and 67.4% were attributable to misconduct including fraud or suspected fraud (43.4%), duplicate publication (14.2%), and plagiarism (9.8%). In addition, the number of scientific articles retracted because of fraud has increased 10-fold since 1975.18

**Management of Ethical Breaches**

The initial assessment of a reported concern requires several key decisions. The first is assigning the responsibility to collect the facts and complaints surrounding the potential breach to the most unbiased and unconflicted group and establish appropriate safeguards to ensure confidentiality. The second decision is whether one should appoint a representative from the legal department to this group; the answer is almost always yes! An attorney representing the department or organization provides ongoing legal advice and in some cases protection of the process by establishing attorney-client privilege. At some point the person accused of a breach may wish to engage an attorney, and this may be as the preliminary investigation is in process or after it is completed. The third decision is whether to engage the communications team. Again, the answer is almost always yes! This group is essential in the process as they can help create clear and unambiguous messaging. Having them engaged early as part of process will also enhance the timelines of communication concerning the issue and its resolution to the organization and public.

Although, there is a lower incidence of individual ethical breaches in academic settings, they do occur, and they require prompt action when identified. It behooves the leader and her or his organization to prepare and to have a system in place to manage these incidents in a timely fashion and with full transparency. The more egregious the complaint, the swifter the necessary action. When the response to such events is delayed, it may give the appearance of being covered up. This perception can erode the trustworthiness of the leaders, the academic health center, or the university. Take a moment to reflect on your organization, examples of such events, how they were managed and how they might have been managed in a better fashion. Three recent cases emphasize the importance of prompt investigation of allegations particularly when they represent egregious violations of moral conduct.
CASE EXAMPLES: Egregious Breach of Ethical Principles

An egregious breach of ethical principles is exemplified by the recently highly publicized case of Larry Nassar, an osteopathic physician at Michigan State University. He is accused of molesting at least 265 young gymnasts over a 20-year period. A second example is that of George Tyndall, a former gynecologist, who made lewd comments and conducted inappropriate intimate exams on at least 52 women across a 26-year period at the University of Southern California, despite repeated complaints against him. Another example is that of Richard Strauss, a team physician at the Ohio State University, accused of sexual abuse by at least 177 men over many years. The allegations came to light in April of 2018 and are thought to have occurred over many years ago. This investigation has been difficult because Dr. Strauss left the university over 20 years ago and died by suicide in 2005. This case points out the problems created by apparent inaction. It is now a matter of litigation and a mediation process.

Apparent lack of administrative oversight of the individuals involved and the inaction as demonstrated in the cited examples are a clear violation our social contract with the public. In these types of egregious cases, the primary concern should be the victims. There was serious harm caused to people as a result inappropriate behavior of individuals. The delayed action on the part of organizations probably exposed unknowing others to harm and earlier action may have protected them. In cases such as these, leadership must publicly and swiftly apologize and take steps to make amends. Furthermore, it has been shown that the investigation of ethical complaints against physicians if not fully and promptly disclosed can discourage individual patients from seeking the care that they need or in complying with physician recommendations, thereby leading to additional harm.

A secondary concern is the reputational impact on an organization. Inaction can not only harm patients but will also harm your institutional reputation. For example, in relation to the Strauss case, the Columbus Dispatch newspaper surveyed 1000 Ohio residents conducted between September 28, 2019 and October 2, 2019. They found 43% of the respondents thought the matter of accusations against Dr. Strauss made their opinion of Ohio State less favorable. Academic Health Centers are built on a strong foundation of trust and not on self-interest. Hence, the success of Academic Health Centers rests on the trust of the public. Not addressing egregious ethical breaches as they occur will sever that trust.

Summary

Ideally, the academic physician executive is an ethical leader who will foster the development of an ethical organization. Further, developing the skill of ethical decision-making will assist the leader in seeing ethical dilemmas in what may seem to be routine decisions. This skill can be learned like other leadership skills such as negotiation and conflict resolution. In order to succeed, we believe the leader must be knowledgeable about the foundation and principles of ethics.

References

2. Federation of State Medical Boards. U.S. medical regulatory trends and actions. Dallas, TX; 2014.


Management of Ethical Issues in Human Subjects and Basic Science Research

KEY POINTS

• Each principal investigator (PI) and co-investigator (Co-I) plays an important triple role: each one must be an excellent researcher, a strong leader, and an ethics advocate.

• The Common Rule, established in 1981, is the fundamental standard of ethics to which any government-funded research in the United States is held; nearly all U.S. academic institutions hold their researchers to these statements of rights regardless of funding source.

• A leader should support education on best research practices and systems to monitor training. One such computer-based learning tool has been developed by the Collaborative Institutional Training Initiative (CITI); content that includes nearly twenty-four subject areas.

• To ensure subject rights, it is the investigator’s responsibility to make sure that subjects are well informed, and all questions are answered.

• The seven requirements for ethical clinical research include Value, Validity, Fair Subject Selection, Favorable Risk Benefit Ratio, Independent Review, Informed Consent, and Respect for Enrolled Subjects.

Leadership in Research

Research is an integral mission of most medical schools and academic health centers. Indeed, universities are ranked based on the amount of their annual research funding. Likewise, faculty are often promoted based on research accomplishments and publication of high impact peer-reviewed articles. Thus, being a leader in research inherently presents individuals with conflict of interest as research funding may not only increase the status of the institution but also that of the individual investigator.
Therefore, it is critical to remember and emphasize that research ought to be conducted to provide new scientific advances and evidence for the ultimate improvement of health care delivery. Furthermore, although research sometimes aids the patients involved in it, the aim of research is really to help future patients and thus presents additional challenges. In order to manage these various outcomes, honesty and compassion must be placed at the forefront of research activities.

Each principal investigator (PI) and co-investigator (Co-I) play an important triple role: they must be an excellent researcher, a strong leader, and an ethics advocate. The duties of these research leaders include being a mentor and role model for residents and trainees and other faculty; encouraging collaboration amongst researchers and ensuring that research is done ethically. The PI and Co-I are moral fiduciaries of the project. In this role, the leader must ensure an underlying culture of ethical research and adherence to these principles.

In addition, the research leader may have a role as an administrator. This may be as a member or even the chair of an Institutional Review Board (IRB) or Research Ethics Board (REB). While clearly the focus should be to ensure ethical research within the environment covered by the board, it is equally important to ensure that the IRB or REB functions efficiently, has adequate representation, and does not ultimately discourage or delay important research from moving forward.

Furthermore, for research to occur, many different aspects of an organization may be involved. Hospitals and universities have many rules and regulations that in some cases may unintentionally hinder research efforts. For instance, even once an approval is obtained, it can be difficult for a trainee, not currently clinically assigned to the hospital to obtain access to the electronic medical records. Thus, given that research is part of the mandate of academic hospitals and universities, it is essential that the research leader understand the importance of research as well as the priority of optimal care of patients and privacy rules designed to protect them. As he or she has a role to highlight research accomplishments of their university, department or division so must they advocate for conducting ethical research as a moral fiduciary.

**Establishing a Culture of Research Integrity**

The doctrines guiding the ethical considerations of human subjects’ research were outlined in Chapter 1. It is essential that the leader ensure that there is an ethical culture and that there is adherence to these principles and the processes established in their hospital and university. The principles regulating safe and ethical human and basic science research are known or should be known to all investigators and key personnel who participate in the design, conduct and reporting of human subjects or other research including exempt research and all IRB members and staff. It is the leader’s responsibility to ensure compliance with these principles. For human subjects’ research these are specified in what is known as The Common Rule established in 1981. This rule includes the ethical regulations in the United States regarding biomedical and behavioral research involving human subjects. A significant revision became effective in July 2018 which includes a waiver for bio-banking. In the United States, this rule governs Institutional Review Boards for oversight of human research and followed the 1975 revision of the Declaration of Helsinki. It is also included in the 1991 revision to the U.S. Department of Health and Human Services Title 45 CFR 46 (Public Welfare) Subparts A, B, C and D. Subpart A. The Common Rule is the baseline standard of ethics by which any government-funded research in the United States is held; nearly all U.S. academic institutions hold their researchers to these statements of rights regardless of funding source.

However, it is difficult to recall the numerous details of rules and regulations guiding research. Hence, the leader and organization also have an obligation to provide access to training and refresher courses in these principles. Many organizations have found it useful to subscribe to online training modules. An example is the Collaborative Institutional Training Initiative (CITI Program). This program “is dedicated to promoting the public’s trust in the research enterprise by providing high quality, peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics pertinent to the interests of member organizations and individual learners.” According to the CITI Program Website, “the educational materials are designed and regularly updated to:

- ‘Enhance the knowledge and professionalism of investigators, staff, and students conducting research in the United States and internationally’
Ensuring Ethical Leadership in Academic Medicine

- ‘Educate members, administrators, and leadership of ethics committees that review and oversee research’
- ‘Promote ethical research at organizations through the education of research administrators and organizational leadership’

Founded in 2000, the CITI Program began with an initial course on Human Subjects Research Protection developed by a group of content experts including the following institutions: Albany Medical Center, Children’s Hospital of Boston, Dartmouth College, Fred Hutchinson Cancer Research Center, Group Health Cooperative, National Comprehensive Cancer Network, University of Kentucky, University of Miami, University of Nebraska Medical Center, and University of Washington. Subsequently, it was expanded to include content for social and behavioral sciences in 2004. Today the content includes nearly twenty-four subject areas including: Animal Care and Use, Biosafety and Biosecurity, Clinical Research Coordinator, Conflicts of Interest, Disaster Planning, Export Control, Good Clinical Practice, Information Privacy and Security, and Responsible Conduct of Research. A new module includes information on the ethical and appropriate uses of administrative data for research. Collectively, these programs reach more than a million learners annually at thousands of organizations. In 2016, CITI joined the Biomedical Research Alliance of New York (BRANY) to better address the needs of the global research community. The website provides information about CITI and how to set up organizational subscriptions and other content information.

The leaders’ role is to ensure an accountable culture of research integrity. This is accomplished by establishing institutional requirements for training which are clearly communicated to all involved with research and include punitive mechanisms for enforcement such as revocation of research approval which would prevent continuation of studies and potentially interfere with ongoing funding or renewals.

Research Subject Rights

When patients are recruited for a study, they must sign a informed consent document signifying their willingness to become subject of the research study. Although they may have started as patients, once they have become part of a study, they are most accurately referred to as “subjects.” The informed consent process itself may be ethically problematic if the consent document is difficult to understand or fails to adequately characterize the risks of the study. Informed consent documents for participation in research are necessarily different and much more detailed than are informed consent forms for treatment. The rights of subjects must be fully respected in human subjects’ research. For this reason, all subjects must be fully informed on the reason for the study and what will be requested of them. Reading and signing a research consent form is usually inadequate and both written and verbal information is generally needed. While a signature on the informed consent form is often obtained by a research nurse, it is the researcher’s responsibility to ensure that subjects are well informed, and all questions are answered.

The World Medical Association Declaration of Helsinki should be followed. This outlines how human subjects should be involved in medical research. Most importantly, subjects should not be placed in situations which would cause unintentional harm. In addition to an oral discussion, subjects should receive written materials, so that they can understand what they are agreeing to. This type of miscommunication is exemplified in the following anecdotal case. A subject who was scheduled to undergo surgery agreed to participate in a clinical trial comparing two protocols to decrease surgical infections. In one arm of the study, subjects/patients were given a bottle of cleanser to use the night before surgery. One subject/patient thought that “cleansing herself” meant that she should clean out her gastrointestinal tract so rather than using the liquid to take a bath, she drank the bottle of cleanser. There were several consequences including delaying the surgery to another day as well as causing embarrassment and potential harm to the subject/patient.

Research leaders must ensure that their institutional research ethics board has been consulted prior to initiation of any patient-related research.
CASE EXAMPLE: Failure to Protect Human Research Subject Rights

A case in point illustrates the challenges to protecting our patients as research subjects and their rights. Jesse Gelsinger died in September 1999 at the University of Pennsylvania, four days after receiving an adenoviral vector encoding a gene important in the metabolism of ammonia.\(^3,4\) He had a mild variant of this X-linked disorder—the severe form is fatal at birth—and had been successfully managed with a restricted diet and specific medications. Death was caused by a massive cytokine release syndrome which led to multiple organ failure. The Food and Drug Administration (FDA) concluded that: a) Gelsinger had laboratory values that should have excluded him from the trial, b) the investigators failed to report the deaths of monkeys given the viral vector in preclinical safety studies, c) the investigators failed to report serious adverse events in two previously treated patients and d) the institution and investigators had financial interests in the research. Medical experts also criticized the scientific merit especially the use of this type vector for gene delivery which results in only transient expression. The ethical lapses of the investigators were compounded by multiple institutional failures of human research oversight.

Fortunately, examples like the one noted above are infrequent. In order to protect our subjects, we must ensure that they are well versed about the research and well aware of possible side effects so that they can decide whether they want to participate in the trial or not. Additionally, when cases occur in which there was an apparent ethical breach, the leader’s role is to oversee the issue and make ethically appropriate decisions to correct the situation in manner consistent with accepted guidelines.

Ethical Requirements for Clinical Research

Mere adherence to the above regulations alone may not be enough to attain an ethically sound research protocol. As research studies occur within diverse settings “case by case differences challenge the rote application of regulations” and may benefit from a generalizable conceptual model of ethical clinical research.\(^5\) In recognition of the unique nature of research, several authors have proposed such a generalized approach to the ethics of clinical research.\(^6\) The requirements are shown in Table 7-1 and attempt to ensure that research subjects are not simply used but also respected. An additional critical component of ethical research is that the research contributes to the social good.

TABLE 7-1: Seven Requirements for Clinical Research

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<th>Requirement</th>
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<td>1. <strong>Value</strong> – Research must enhance health or knowledge.</td>
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<td>2. <strong>Validity</strong> – Studies must adhere to a rigorous and scientifically valid methodology.</td>
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<td>3. <strong>Fair Subject Selection</strong> – Vulnerable populations should not be targeted for risk prone research nor should beneficially research favor privileged groups.</td>
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<td>4. <strong>Favorable Risk Benefit Ratio</strong> – Risk to individual Subjects must be minimized while benefits are enhanced and the potential overall gain for society must outweigh the studied risks.</td>
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<td>5. <strong>Independent Review</strong> – Independent bodies not affiliated with the research must be available to review, approve, amend or cancel a study.</td>
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<td>6. <strong>Informed Consent</strong> – Subjects must be informed of the research and give voluntarily consent with the stipulation that the consent may withdraw at any time.</td>
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<td>7. <strong>Respect for Enrolled Subjects</strong> – Subjects should have appropriate privacy protection, the right to withdraw from the study, access to information regarding any results or new risks and their well-being monitored.</td>
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References


KEY POINTS

- The definitions of research misconduct including Fabrication, Falsification, Plagiarism are clear, but detection is difficult.

- Although the Common Rule specifies annual reviews of research projects to detect research related events, patient complaints, and protocol deviations, these will likely be unable to detect data falsification.

- The Federal definition of Research Misconduct is discussed as well as the origins of the Office of Research Integrity. A case example of research fraud is used to show how difficult it can be to detect as well as the unfortunate impact on the unknowing public and patients.

- The issues concerning author order and that of dual primary or senior authors in discussed.

- Committee on Publication Ethics (COPE) provides guidelines to authors, institutions, and journals to address issues of authorship should they arise.

We are all very aware of the steps in completing a research study. Initially, the published literature should be reviewed to determine if previous similar studies have been published and if not, the search is followed by formulating a research question to be answered. Subsequently, the study needs to be reviewed and approved by the Institutional Review Board (IRB) or Research Ethics Board (REB). Once approved, the study is implemented, data collected and finally the results analyzed, and the study written and submitted for publication. We must reemphasize that the principal investigator is not only the scientific lead for a project but also the moral fiduciary. He or she has the inherent responsibility to ensure that the research is done ethically which generally means that it is following the protocol and meeting accepted guidelines for ethical research. Once completed, the results should be published whether they are positive or negative. It is always easy to publish studies with positive outcomes, but we believe that it is equally as important that negative results are published. Negative results may change care for patients in the future just as those with positive results do. From the public perspective, having the study published confirms that their participation was of value whether the results are positive or negative.
Another sometimes contentious issue is determining who the primary author of the research report should be and which other individuals should be included as well as the order of the authors. This needs to be discussed among the research team. Research leaders should ensure that all those individuals participating in a project, who may not meet authorship criteria, have the opportunity to contribute in a way that does meet authorship criteria so that they obtain academic credit for their work, and are introduced to research productivity in a positive way. The leader may be asked to intercede, if there are disputes concerning the validity of the data and interpretation and authorship. However, many times investigators, particularly junior faculty or trainees are reluctant to ask the department leader to help resolve the conflict as they may fear being exposed to retribution. Cases may be unusually complex with multiple layers of potential conflict and power inequity.

Effective leadership requires that all faculty, particularly those in junior roles, research assistants and technicians understand that reporting of issues of data validity and authorship are essential for maintaining academic integrity. Further, those bringing forward such complaints must be protected. In such cases, the necessary institutional investigation requires confidential objective assessment without personal bias and adequate time to fully understand and debate the issues. As with other decisions, the leader may wish to convene a departmental committee or consult with research leaders outside the academic unit to help review these disagreements particularly if they are very contentious.

One of the most serious ethical issues in research is academic fraud. There has been increased awareness of fraud and misconduct in research as noted in Chapter 6. There is some evidence that academic fraud occurs more commonly than one would expect. Some of the reasons cited for this include academic pressure to write and publish articles; personal desire for fame; one’s ability or inability to write an article; inability to determine right from wrong; and often financial gain. For researchers who work collaboratively with industry, results may be changed so that the product appears to be more effective. This may have multiple benefits for industry as well as for the investigator including earlier approval by the FDA, potentially higher sales, and greater revenue. The investigator may receive financial and other rewards from the company as well.

The Office of Research Integrity Website provides an excellent overview and historical background describing the genesis of oversight for research integrity in the U.S. In 1981 research misconduct became a public issue in the U.S. when the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held the first hearing on the emerging problem. This was prompted by the public disclosure of research misconduct cases at four major research centers in 1980, including the report of a physician who was employed by Emory and Harvard who was accused of forging data that formed the basis for over 100 articles. Some twelve cases of research misconduct were disclosed in this country between 1974–1981. Congressional attention to research misconduct was maintained throughout the 1980s by additional allegations of research misconduct and reports that the major federal funding agencies including the National Institutes of Health (NIH), universities, and other research institutions were not adequately responding to those allegations. New federal regulations were subsequently developed requiring institutions to investigate allegations of research misconduct. In 1985, Congress acted by passing the Health Research Extensions Act. This Act added Section 493 to the Public Health Service (PHS) Act that required the Secretary of Health and Human Services to issue a regulation requiring applicant or awardee institutions to establish an administrative process to review reports of scientific fraud and “report to the Secretary any investigation of alleged scientific fraud which appears substantial.” Following this, in March 1989 the federal government established the Office of Scientific Integrity (OSI) in the Office of the Director of the NIH, and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH). The sole purpose of these offices was to deal with research misconduct. In addition, the creation of OSIR also began the process of removing responsibility for research misconduct oversight from the funding agencies. In May 1992, OSI and OSIR were consolidated into the Office of Research Integrity (ORI) in the OASH. The purpose of the ORI was to respond to and investigate allegations of scientific misconduct as well as promote integrity and responsible research practices. As part of this initiative the ORI developed definitions and guidelines regarding research misconduct. Later that year, HHS established a process for all scientists formally charged with research misconduct to have a hearing opportunity before the Research Integrity Adjudications Panel of the Departmental Appeals Board, HHS. The HHS adopted a definition of research misconduct that was developed by the National Science and Technology Council. This was published in the Federal Register on October 13, 1999. The Federal Research Misconduct Policy containing the final definition was published in the Federal Register on December 6, 2000. Accordingly, all extramural research institutions were required to provide training in the responsible conduct of research to all research staff with direct involvement in proposing, performing, reviewing, or reporting...
research, or who receive research training, or support by PHS funds. Subsequently, the research and educational initiatives on research integrity included collaboration with the AAMC including an educational program for institutional research integrity officers. The ORI published the definitions of research misconduct including Fabrication, Falsification, Plagiarism as shown in Table 8-1. The Office of Research Integrity was established in 1992 to respond to allegations and promote research ethics.

<table>
<thead>
<tr>
<th>TABLE 8-1: Federal Research Misconduct Policy*</th>
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<tr>
<td>• <strong>Fabrication</strong> – making up data or results and recording or reporting them.</td>
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<tr>
<td>• <strong>Falsification</strong> – manipulation of research materials, equipment or processes or changing or omitting data or results such that the research is not accurately represented in the research record.</td>
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<tr>
<td>• <strong>Plagiarism</strong> – appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.</td>
</tr>
<tr>
<td>• <strong>Differences of Opinion</strong> – not included in research misconduct.</td>
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*Research misconduct is defined as fabrication falsification or plagiarism in proposing performing or reviewing research or reporting research results.


**CASE EXAMPLE: Research Fraud and Conflict of Interest**

In 1998, Andrew Wakefield and colleagues published a case series in the *Lancet*, which suggested that the measles, mumps, and rubella (MMR) vaccine may predispose to behavioral regression and pervasive developmental disorder in children. Although the study had a small sample size (n = 12) and an uncontrolled design, and the conclusions largely speculative, the paper received wide publicity. The consequence was that MMR vaccination rates began to drop because of parental concern about the risk of autism after vaccination. Very soon epidemiological studies were conducted and published that refuted the association between MMR vaccination and autism and questioned the reasoning. In response a short retraction of the original data and the conclusions was made by 10 of the 12 co-authors of the paper; in essence stating that there was no causal link between MMR vaccine and autism as the data were insufficient. This was accompanied by a disclosure by the *Lancet* that Wakefield et al. had failed to notify them of financial conflicts of interests related to the study. Wakefield had been funded by lawyers who had been engaged by parents in lawsuits against vaccine-producing companies. Although in 2004 the *Lancet* initially exonerated Wakefield and his colleagues from charges of ethical violations and scientific misconduct. The *Lancet* completely retracted the Wakefield et al. paper in February 2010. The final episode in this example was that in 2011 Wakefield et al. were determined to be guilty of deliberate fraud as they had falsified facts by picking and choosing data that suited their case. As reported by Sathyanarayana and Chittaranjan, the British Medical Journal published a series of articles on the exposure of the fraud, which appears to have taken place for financial gain. These authors further stated that this case was of great concern in that the investigation and subsequent exposure was the result of journalistic investigation rather than an investigation by an academic enterprise with implementation of corrective measures. They conclude “Scientists who publish their research have an ethical responsibility to ensure the highest standards of research design, data collection, data analysis, data reporting, and interpretation of findings; there can be no compromises because any error, any deceit, can result in harm to patients as well harm to the cause of science, as the Wakefield saga so aptly reveals.” Even with the evolution of requirements for institutions to establish processes to ensure research integrity systematic failures can unknowingly permit fraud. The case described is likely one of the most serious examples of scientific fraud in medical history.
Fraud in research is difficult to detect, investigate and resolve as evidenced by the case example of Wakefield that took nearly 13 years to come to closure. Furthermore, most research review boards do not prospectively track published articles from their institutions to verify that appropriate reviews to protect human subjects have taken place. Although the Common Rule specifies annual reviews of research projects to detect research related events, patient complaints, and protocol deviations, these will likely be unable to detect data falsification. As such, organizations are in fact dependent on anonymous whistle blowers to detect fraud. Hence, it is essential that institutions implement anonymous reporting systems that allow reporting of ethical concerns that protect the whistleblower as well as processes and procedures for investigating complaints in a confidential manner. If fraud is identified, then it is an organization’s responsibility and that of the leaders to report the findings and insist on the retraction of the manuscript by the principal investigator. The incident should be reported to federal authorities if federal dollars were used to complete the work. Finally, appropriate sanctions and punishment should be leveled against the investigator according to the institution or university guidelines.

The major challenge is not in defining fraud, but rather detecting it in a timely manner as it may go unrecognized until anonymously reported. A second case in point will further illustrate the serious nature of fraud and its impact on patient treatment, how difficult it can be to detect, and the responsibilities research institutions have in auditing compliance with human research standards.

**CASE EXAMPLE: Research Fraud and Its Deleterious Impact on Patient Care**

In the late 1980’s there was a broad effort to improve the treatment of advanced stage breast cancer with high dose chemotherapy followed by bone marrow transplantation. The programs offering this treatment rapidly grew in the United States as well as internationally. Among the most recognized and successful of these investigators was Werner Bezwoda an oncologist at the University of Witwatersrand in Johannesburg, South Africa. In 1992, he reported that the “dose-limiting barrier “had been overcome. He reported that over 90% of patients who received the mega dose regimen had achieved a complete response. The treatment was expensive and associated with substantial risks. Clinical trials were underway. At large academic centers case volumes increased to several dozen per week. The landscape was complicated by the fact that the procedure was considered experimental by insurers as clinical trials were underway. In many trials there was no survival benefit that could be identified but in one that was led by Bezwoda phenomenal survival benefits were reported. Patients did not want trials, they wanted treatment. Accrual to trials was extremely poor. Patients began filing requests for insurance providers to pay up to $400,000 for these procedures and when denied lawsuits were filed against the insurance company. Patients were driving their own care. In all 86 lawsuits were filed between 1988 and 2002 and in 47 instances the patients won the case. Aggressive chemotherapy and bone marrow transplantation for treatment of breast cancer was being mandated by law. Between 1991 and 1999 about 40,000 women globally had undergone this treatment. The value of the treatment was being challenged as the clinical trials slowly continued. Bezwoda presented an update of his research program at the annual meeting of the American Society of Clinical Oncology (ASCO) in 1999. The results were spectacular. That same day three other trials were presented and reported no survival benefit of the treatment. In December of 1999, a team of American investigators requested that Bezwoda allow them to visit his institution so they could review the results and learn how his group was reporting incredible results compared to the findings of no survival benefit in other studies. The team of investigators uncovered a research study in shambles. The entire research project was fraudulent. According to one report “the audit team reviewed more than 15,000 patient records from two hospitals in a search for records of the 90 patients in the 1985 study. It also looked at research documents and minutes covering 15 years of meetings by the University of the Witwatersrand Committee for Research on Human Subjects to verify that the trial’s protocol had been reviewed and approved. The auditors found records for only 61 participants. In 27 there was enough documentation to determine whether they were eligible for the study. Of these, 18 were obviously not eligible to participate. Only 25 seemed to have

**continued**
received the therapy that they had been assigned and all but three of these were in the high-dose therapy/ transplant group. Although Dr. Bezwoda reported that there were no treatment-related deaths, the auditors noted that they had found at least three possible treatment-related deaths in the high-dose group. No patient consent forms were found, and the auditors concluded that the protocol was not written until the 1999 study was audited. The auditors also concluded that Dr. Bezwoda lied in this study and reports of nine other clinical trials when he wrote that his institution approved the protocol. He eventually admitted his error, apologized to the scientific community, and resigned from the University of the Witwatersrand in Johannesburg.

It became apparent that the protocols and studies had never been reviewed by the IRB. Prior to the scandal, no one at the University of the Witwatersrand questioned whether a published study had met internal requirements, according to Peter Cleaton-Jones, MB, BCh, PhD, DSc (Dent), DPH, chair of the University’s Institutional Review Board. “We have an extremely strict policy before a study is done, but up to the present time, we have not checked backwards. The logistics of this are overwhelming,” he said, adding that the University is reconsidering its policy.

This case example illustrates the complexity of identifying fraudulent research and how serious the ramifications can be to the public and health care providers far beyond the institution where the fraud occurred. Even the most rigorous research integrity programs will not detect the egregious fraud without having anonymous reporting systems, whistle blower protection and an institutional commitment to ethical research practices and establishing an ethical culture.

**Authorship and Publication**

Authorship in academia contributes to hiring and promotion processes. Hence, one of the more difficult issues is determining who should be the primary author and with other individuals, who should be included and what is the order of the authors. Today, the vast majority of biomedical publications have more than one author, and the number of authors per publication is rising exponentially as a function of time. For multiauthor papers in the biomedical sciences, the order in which authors are listed is a code for conveying the importance of their contributions. The first author is typically assumed by the individual (usually a junior person in training) who does the bulk of the work in the study, whereas the last position is taken by a senior person who has supervised the work. Hence, the author position is essential for attributing contributions from junior investigators. These junior investigators need first-author publications to further their careers in biomedical research and when merited should be given that opportunity. The author order should be discussed and agreed to by the research team.

Although practices will vary amongst institutions and even individual labs, the majority of academic health centers have adopted policies that guide authorship. Faculty, trainees, or other individuals who did or participated in the study are commonly recognized as an author. In addition, many journals have established rules to determine who qualifies for academic authorship. No longer can the role or status of authors be determined solely by the position of their names in the author byline. The current trend is for each manuscript to note the nature of the contribution of each author.

Many journals follow guidelines set by the International Committee of Medical Journal Editors (ICMJE), which created a list of recommendations to clarify the definition and responsibilities of an author. Despite these definitions, no criteria have been outlined for defining first author, nor have any recommendations been made in regard to author order. By tradition in medical literature, if not listed alphabetically, the first author makes the largest contribution and the last author is the most senior or principal investigator. Despite this tradition, there are no firm guidelines in place to ensure or guarantee a fair interpretation of authors’ contributions. As multicenter studies and multiauthor collaborative research and publication grow, the role of the traditional first author is becoming less important. This is problematic in that authorship and author order are used to determine academic achievement for the purposes of promotion, allocation of research time, and funding.

This mechanism for credit attribution worked reasonably well when there were 2 authors but is less clear as research groups now publish studies with numerous authors making important contributions. Consequently, recent years have witnessed a practice whereby the first or last author positions in the byline may be shared by 2 or more individuals. Shared co-first authorship is defined as two or more authors who have worked together on a publication and contributed equally. This practice can lead to confusion in appropriate recognition of the role of each coauthor. Thus, the equal contribution is often indicated in the fine
print of a published paper or in an investigator’s curriculum vitae. To complicate matters, there is some evidence suggesting sex bias skewing how authors are listed in the first position among coauthors. While suggestions have been made to make equal authorship more findable in databases, in-text citations, and bibliographies, no unified system has been created.

As a result of the aforementioned issues, determination authorship is more complex today. As such, arguments about authorship and publication are a serious issue for the academic leader. He or she should strive to do the right thing and resolve the dispute while adhering core ethical principles. This is particularly complicated if the study involves multiple institutions nationally or internationally. As with other difficult issues one option for the leader is to make use of an established Ethics Committee, a committee on research integrity, or an institutional leader appointed to oversee such complaints such as the Vice Chair, Vice Dean or Vice President of Research. If a committee or mechanism does not exist, then the leader should weigh the options in consultation with organizational leaders. It is valuable to seek internal consultation for advice on the specific issue.

These disagreements can be very contentious and difficult to navigate. Fortunately, the Committee on Publication Ethics (COPE) provides guidelines to authors, institutions, and journals to address such issues when they arise. COPE was founded in 1997 to address breaches of research and publication ethics. COPE has published guidelines with the aim to “find practical ways of dealing with the issues and develop good practice”.

The link referenced provides access to the initial guidelines in 1999. COPE provides web access to a number of guidelines including journal management, ethical oversight, intellectual property, allegations of misconduct, complaints and appeals, conflicts of interest and competing interests, and post-publication discussions and corrections. (Table 8-2).

In addition, the International Committee of Medical Journal Editors defines the role of authors and contributors based on four criteria as shown in Table 8-3.

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<th>TABLE 8-2:</th>
<th>Links to COPE Guidelines and Flow Charts*</th>
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<th>TABLE 8-3:</th>
<th>The International Committee of Medical Journal Editors Defines the Role of Authors and Contributors Based on These Four Criteria</th>
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<tr>
<td>1.</td>
<td>Substantial contribution or design of the work or the acquisition, analysis or interpretation of data for the work</td>
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<td>2.</td>
<td>Drafting the work or revising it critically for important intellectual content</td>
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<td>3.</td>
<td>Final approval of the version to be published</td>
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<tr>
<td>4.</td>
<td>Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.</td>
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References

ENSURING ETHICAL LEADERSHIP IN ACADEMIC MEDICINE


KEY POINTS

• The role of the mentor is a fiduciary one and its foundations lie on loyalty and trust.
• A mentor is not a synonym of a supervisor, instructor, faculty, trainer, coach, or boss.
• An academic leader in the surgical field has an ethical duty to provide an environment which supports nurturing, developing, and enhancing mentor-mentee relationships.
• A reliable mentor hones the acquisition of knowledge, expertise, and judgment in mentees to advance and progress not only in the professional but also the personal life.

Introduction

The modern use of the nouns mentor and mentorship may be traced to the American business scenario and other social movements in the late ’60s. The historical roots of the term mentor and mentorship have been well described. The significance of mentorship was underscored by the Yale group of social scientists led by Levinson: they emphasized the role of the mentor as the key factor in order to accomplish the goals of another individual. In his Presidential Address when inducted as President of the New York Academy of Medicine, Jeremiah Barondness introduced the concept of mentorship in the medical field, by analogy to the relationship between Bill Dickey and “Yogi” Berra, both New York Yankees’ catchers. The last one used to say referring to Dickey “Bill is ‘learning’ me his experience.” This phrase summarizes in a quite simple and straightforward fashion the core of this relationship. In the surgical arena, Edward Copeland III referred to the importance of this relationship in his Presidential Address for the American College of Surgeons. From that moment on, the concept of mentorship in Surgery has gained widespread recognition and importance as a key for success in the professional field.
CHAPTER NINE: Ethical Issues Involving the Trainee: Mentoring, Resident Autonomy and Research

The Role of the Mentor and Framing the Mentor-Mentee Relationship

As per the definition of the Oxford English Dictionary, the mentor is an experienced and trusted advisor. It represents someone who sees more talent and ability within you than you see in yourself and helps to bring it out of you. In the medical and surgical academic settings, the UK Standing Committee on Postgraduate Medical and Dental Education defines mentoring as “the process whereby an experienced, highly regarded, empathic person (the mentor) guides another individual (the mentee) in the development and examination of their own ideas, learning and personal and professional development. The mentor, who often but not necessarily, works in the same organization or field as the mentee, achieves this by listening and talking in confidence to the mentee.”

Another approach is that of, “an active partner in an on-going relationship who helps a learner to maximize his or her potential and reach personal, professional goals … [resulting in] … a personal developmental relationship in which a person with greater knowledge or experience helps another with less”.

Mentoring has been addressed frequently within the surgical academic arena, and its importance and impact in future generations have been emphasized by several authors. Both clinical medicine and medical research are particularly suited to the mentoring process. Both activities are fundamental to ensure progress in academic surgery, and to be promoted in the leadership pyramid. The human touch, an ongoing and continuous supervision and a slow accrual of experience are central in order to hone the mature discernment which conveys success in this field. Most faculty in a position of leadership and a prominent role can and need to identify individuals in their early stages capable of starting up the academic and leadership ladder. Initially this mentoring relationship fostered by faculty in leadership positions will be focused in relative particular areas, such as: personal attitudes and qualities, interaction with others, adherence to regulations, or problem solving approaches. Usually, the full development of an academic faculty in her or his triple role as educator, researcher and physician requires someone to obtain several different mentors with specific areas of expertise. An additional trait is the emotional backup mentors provide to their mentees, providing an emotional attachment of the mentee to the mentor, with important ethical implications. Understanding the mentor-mentee relationship and its ethical boundaries is key for those in leadership positions to strengthen their influence and provide for the wellbeing of their mentees.

Within the discipline of surgery, mentoring is strongly supported by different surgical associations. The Royal College of Surgeons of England highlights the potential benefits of these positive interactions, including career success, job satisfaction and improved working relationships with colleagues and patients. In the same direction, the American College of Surgeons has also recognized the importance of mentoring in surgery and its impact in academic development. The importance and the necessity for surgical mentoring to evolve to meet the changes in the population our current mentees was recognized by Dr. Keith Lillemoe in his Presidential Address before the American Surgical Association in 2017. What worked in the past with over 90% of surgeons being white males doesn’t work today with the increase in the number of women and a more ethnic and racially diverse group of surgical trainees and faculty. Mentoring needs to evolve to keep pace with the evolution of surgery to a gender neutral and multicultural profession.

Based on the phases of the relationship model of mentoring, developed by Mary Wheeler and Michelle Cooper, many consider mentoring as a 6 phase or stage relationship as shown in Table 9-1 and Figure 9-1.

So, the central question is the following: What does the mentor need to do and achieve on behalf of his or her mentee? The mentor furnishes a high level of know-how, wisdom, experience, and governance to raise and promote the mentee to a higher level of performance and achievement and also to hone the personal qualities of the disciple. Mentoring is the long term passing on of support, guidance, and advice. Most times, this is a role to be in the hands of natural leaders in their field, and that is the reason leadership and mentorship so frequently go paired hand-in-hand. It is important to distinguish between a mentor and other important roles such as a trainer, a coach, or simply the one who teaches another how to perform a procedure. Coaching is more about developing individual skills and knowledge in order to perform better and improve one’s achievements at work or another activity and tends to be more formal and goal-related than mentoring.
CHAPTER NINE: Ethical Issues Involving the Trainee: Mentoring, Resident Autonomy and Research

TABLE 9-1: The Six Phases of Mentorship

1. Develop goals related to the purpose and objectives of the mentor-mentee relationship. You and the mentee should answer to two questions: 1) Why do I need or want a mentor? 2) Why do I want or need to be a mentor?

2. Develop a partnership represented by the alignment of the mentor and mentee. The initial challenge is how to start the relationship and walk through the first stages. The recommendation is to have a sincere and open discussion about what each side is looking for as well as if both sides have available time and support the efforts in this relationship.

3. Prepare a plan and outline. Answers should be determined for these two questions: 1) How I can achieve my goals? and 2) How we will work together?

4. Be patient, as it cannot be expected that from day one the expectations are going to be fulfilled by both sides. Time and mutual understanding are two factors leading to success or failure, besides trustworthiness and loyalty.

5. Determine how you will measure success. This may be represented by promotion, publication, recognition, etc.—leading to increased success of the mentee.

6. Continuous assessment in needed. Both the mentor and mentee need to decide if they are willing to continue nurturing the relationship, if the results are the expected ones, if they feel comfortable in each situation or if it is time to bifurcate paths and seek other goals. (Figure 9-1).

![FIGURE 9-1: The six phases of mentorship.](image)

Traditional mentoring usually reflects the fact that the mentor is more senior and often older than the mentee. But the opposite may be also useful. Reverse mentoring was proposed by Jack Welch, former General Electric CEO, in 1999 with the goal of his top executives learning how to use the internet with the support of the company’s junior associates. More recently, reverse or upward mentoring has changed the traditional hierarchical approach or elder/younger pairing to a relationship where the more senior person is placed as the primary learner and the junior provides his or her experience in a particular field not that amendable to the elder one. This approach provides leader and senior management levels a way to stay in touch with their organizations and the younger cohorts. An example of reverse mentoring is the adoption new technical skills, such as laparoscopy and robotics, by senior faculty. Another example is the use of the electronic health record. Which one of us has not learned to use the EHR more effectively and efficiently from our residents. These are unique opportunities for senior faculty to better understand staff and trainees who are from a younger generation such as millennials.
Another situation for leaders to consider is succession planning, meaning the development of a strong pipeline of capable and potentially successful leaders. It is not just to warrant present and current success but to set the institution or organization up for success tomorrow as well. That means keeping an eye on the present but another one on the future. It is also important that both sides agree to have a clear “contract”, representing in a clear and trustful way the expectations of both. The relationship should be led by the mentee, since it is about building or improving their skills and confidence, they are requested to be proactive and responsible for their demeanor. As said before, many times the mentor will need to provide emotional and psychological support. It is important for the mentor to be a role model who is genuine, available and non-hierarchical in her or his relationships.

It is also important how to define success in your mentoring relationship. Which will be the evidence and the elements of success? It is also mandatory to identify as soon as possible if your mentor or your mentee is not the one for you. Many times, it is just about feeling or rapport, and others about different approaches and perspectives. The mentor needs to balance advice with support as well as developing listening skills.

The mentor needs to comply with the so-called five A’s: altruism, availability, accountability, activity and appreciation. Altruism is related to the fiduciary duty of the mentor to act in the mentees best interest and not his own. The ethical obligation of leaders and mentors is to place the mentees welfare and benefit above their own self-interest. The position of the mentor as a fiduciary implies being “a person holding the character of a trustee, in respect to the trust, confidence, good faith and candor which it requires and having the duty to act primarily for another person’s benefit in matters connected with such undertaking.” In other words, the mentor must be beneficent and serve the best interests of the mentee with a strong duty of good faith. Honesty, virtue, and a mentor-mentee relationship based on a fiduciary role by the mentor ensure the success of the relationship. Some important elements to underline are purpose, communication, trust, process, progress, and feedback. Some key qualities demanded from a mentor are:

- Willingness to communicate what you know
- Compassion and authenticity
- Honesty and candor in the communication process
- Ethical support and protection
- Objectivity and fairness
- Commitment to a successful relationship

Mentoring Trainees in Clinical Care

A core issue with societal trust is the degree of autonomy allowed to resident physicians. This may not seem a major management challenge but is not an infrequent concern of patients. Hence, it constitutes one of the ethical dilemmas faced by academic physicians and those in leadership roles. Patients are increasingly “savvy” regarding medical decision-making. In academic medicine and surgery, a patient concern is “who will be doing my procedure and providing my care.” For academic physicians one of their mission-based responsibilities is to train the future generation of physicians and surgeons. This requires that trainees have direct involvement with patient care and procedures. The teaching physician is the leader in the clinical encounter with the patient and has the ultimate responsibility for the care of the patient and the supervision of any trainees involved in the patient’s care. What is the responsibility of the attending physician and the institution in obtaining informed consent for a resident’s involvement with a procedure? Usually the consent for treatment authorizes the named teaching physician “and/or such assistants as may be selected and supervised by him or her.” Is this sufficient? In most situations the answer is yes, however, not always. In the case of Dingle vs. Belin (Dingle vs. Belin, 749 A2d 157 (Md 2000), the court of appeals found in favor of Dr. Dingle but noted that a cause of action for breach of contract may be valid in such a case. The article addresses the ethical responsibilities of the attending physician according to the AMA Code of Medical Ethics.
“The patient has an interest in the medical procedure, and there is a need for disclosure and agreement if there is likely to be significant participation by other persons. The lack of a clear understanding prior to the procedure may prompt a later finding that a true informed consent was not obtained. Accordingly, specific allocations of duties, if any, should be accounted for realistically and discussed with the patient. When a patient makes demands, the physician can choose to accommodate when possible or desired, or he or she can refer the patient if the demands compromise his or her ability to effectively perform the procedure. The underlying obligation of veracity is expressed in Opinion 8.12, Patient Information, stating that "it is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients" [American Medical Association. Opinion 8.12 Patient information. Code of Medical Ethics. Accessed August 19, 2004.10]. In addition to an honest discussion with the patient, it would be prudent for patient and surgeon to document any agreements or allocations of duties on the informed consent form.”15 (Junge M. 2004; p. 454.)

We believe the academic physician has dual responsibilities. First is the moral responsibility to provide care to the patient. Second, and equally important, is training the next generation of physicians. Being honest and transparent about both of these responsibilities will comfort patients. For patients receiving care at a teaching hospital, it is helpful to communicate the appropriate expectations: they will have students and residents involved with their care, the attending is ultimately responsible and the outcomes with this team approach are superior.

Mentoring Trainees in Research

Faculty who supervise trainees become models for them both through explicit and hidden means. It is an opportunity to teach them how to write grants, implement and complete projects, collect and analyze data, write manuscripts, and publish their work. However, it is most important and yet less emphasized explicitly, to teach them the principles of conducting research so it is done ethically, that patients (if the research includes patients) are respected and that outcomes have the potential to improve patient care. Throughout any given project, there is always an opportunity for teaching the ethics and communication skills needed to do excellent research. Mentors also have the responsibility to ensure that residents receive credit for their work, especially given the varying power dynamics and hierarchies that exist in academic institutions and research teams. In most instances, authorship should be explicitly discussed, and the resident should be the primary author with the mentor being the senior author in most instances. When appropriate, the trainee should also be given the opportunity to present her or his work with support from their mentor. For instance, when possible the mentor should help prepare the trainee for their presentation, provide critical feedback and guidance on answering audience questions, and whenever possible, attend in person.

Potential Issues in the Mentor-Mentee Relationship

The analysis of the lives of different successful individuals shows that most of them recognized the impact of a very influential mentor at some stage of their lives. But there are plenty of failed mentor-mentee relationships. According to G. Steiner, there are three main classifications of a mentor and a mentee relationship16:

• Those masters who, literally, have destroyed their mentees
• Those mentees who have betrayed and harmed their mentors
• The exchange or “eros” of mutual confidence, which should be the goal of every mentor-mentee relationship so as to be successful and mutually beneficial

There are many examples of failed mentor-mentee relationships, from Socrates (470 BC–399 BC) and Empedocles (450 BC–404 BC) to Tycho Brahe (1546–1601) and Johannes Kepler (1571–1631), Edmund Husserl (1859–1938) and Martin Heidegger (1889–1976). In order to prevent failures, Ethics needs to surround the mentor-mentee relationship in several ways.
There is a moral responsibility on each side of this dyadic relationship which represents an essential component of surgical academics and lies at the core of professionalism. The principles of biomedical ethics developed by Beauchamp and Childress (beneficence, nonmaleficence, autonomy and justice) are the foundation and serve as a powerful tool when addressing ethical conflicts in this area.\(^{17}\)

- **Beneficence:** Is linked to the concept of the moral virtue of acting for the benefit of other or others. This ethical principle is related to the fiduciary duty of the mentor towards the mentee.

- **Nonmaleficence:** Refers to the duty of not resulting in harm to others. It is grounded on the “Primum non nocere” dictum, wrongly attributed to Hippocrates and corresponding to Auguste Chomel, a French pathologist, and successor of Laennec (1788–1858).

- **Autonomy:** Refers to the right or condition of self-determination by everyone. From a stricter point of view, (and following Kant's moral concepts) autonomy refers to the ability of an individual to act accordingly to morality rather than under the influence of desire. Liberty and will are prerequisites for the achievement of individual autonomy in the sense to be free of external pressures and free choice.

- **Justice:** According to the Aristotelian concept it should be understood as “rendering to each individual what is due to him or her,” meaning what is lawful, fair and equitable and otherwise, correction to solve or prevent disparities.

So, the ethical principles overlie the mentor-mentee relationship on both sides, but more importantly the mentor and leader should be aware of the ethical implications to be displayed in order to achieve an egalitarian partnership. Very briefly, it may be considered that this relationship should demonstrate the following characteristics: a) the promotion of benefit, welfare, trustworthiness, reliability and loyalty, b) the respect of each other’s rights and dignity and c) honest behavior.\(^{18}\)

Mentors should focus on the benefit and promotion of their mentees. Probably, from an ethical point of view, the concept of beneficence should stand in the highest position and play a core role. Ethical issues are not always so sharply defined in the scenario of surgical mentoring. How do you suggest the best opportunities for your mentee when there maybe opposing ideas regarding what is the best for a trainee? Different proposals may reflect different ideas, cultures, ways of life, beliefs, ethnicities, and backgrounds. In this sense the mentor needs to be extremely careful and always put herself or him in the position of the mentee, and not be guided by personal beliefs.

Future conflicts of interest between mentor and mentee should be prevented. The best way to do this is by means of a truly clear understanding of the “contract,” that is, the goals, reasons, implications and purpose of the relationship. Clear and precise communication between both sides is mandatory and should be open, sincere and proactive to solve differences. If these differences persist over time or if disagreements cannot be solved, the relationship should be interrupted in order to prevent harm to either party.

Since it is imperative for a leader to be a mentor, the misuse of power represents a particular concern and can give rise to predatory mentoring. There have been many examples of abuse of position. One of the expectations of the leader is to create a safe and nurturing environment devoid of sexual harassment, bullying and expression of implicit bias. These expectations must be communicated clearly to the staff, learners, and faculty along with explicit policies for non-compliance.

At its best, mentoring is an altruistic commitment, but may be distorted in the real world of academic surgery. Leaders bear a responsibility to prevent this from happening and if discovered or detected, proceed diligently to its immediate termination as well to ban those involved. Unscrupulous mentors tend to seek vulnerable individuals pursuing a dream, and there are several ways to harm these individuals, prone to accept a hierarchical distance. Predatory mentors are manipulative and will be prone to feed inaccuracies as well as misrepresent their intentions in interacting with their supposed mentees with the goal of their own profit. Mentees in this situation often feel misunderstood, underappreciated, undervalued, overworked and betrayed. Many times, such distorted mentor-mentee relationships are the reason for the interruption of potentially brilliant careers in academic surgery.

To avoid conflicts, it is reasonable to consider a mentor for a faculty member who is not one of their direct reports. For example, there may often be conflicts between a junior faculty member and their Division Chief related to compensation, OR time or space assignments. It is important for mentees to have someone to turn to for advice who is not their direct boss.
Nonetheless, any of the sides of these dyadic relationships may incur power inequities. A very stringent adherence to the four ethical principles may be helpful to set appropriate limits and prevent power asymmetries. Some examples of this inappropriate behavior are the following: exploitation, bullying, harassment, and sexual abuse.\(^{19}\) In summary, a true and exemplary mentor should be a master of virtues and a moral role model and take the steps shown in Table 9-2.

<table>
<thead>
<tr>
<th>TABLE 9-2: Mentor Do’s</th>
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<td>• Need to be an individual of virtues and a moral role model</td>
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<td>• Excel in your own surgical practice</td>
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<tr>
<td>• Disseminate the ethical principles requested to frame the mentor-mentee relationship</td>
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<tr>
<td>• Exert a fiduciary and altruistic behavior towards your mentees</td>
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<tr>
<td>• Think of mentees as your children: prepare and teach them to be autonomous</td>
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<td>• Teach, teach, and teach</td>
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<tr>
<td>• Provide your mentee with honest and clear feedback</td>
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<tr>
<td>• Show professionalism, moral concerns and social accountability</td>
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<tr>
<td>• Be available not only for professional issues but also personal ones</td>
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<tr>
<td>• Be supportive and tolerant</td>
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<td>• Be kind and honest</td>
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Summary

Leaders, in their role as mentors, should very carefully follow ethical behavior and standards. The role to be achieved by the mentor is a fiduciary one, seeking the benefit and the progress of the mentee and the four ethical principles should guide the mentor-mentee relationship. Some of the values pertaining to this bond are integrity, loyalty, fairness and honesty. From the beginning of a mentee-mentor relationship, a clear “contract” regarding goals to be pursued and details (time and availability) is necessary. In addition, active and truthful communication between both sides is prerequisite.

References

\url{http://dx.doi.org/10.1016/j.ijsu.2014.08.395}.


KEY POINTS

• Although market forces are the primary determinant of physician compensation, ethical issues involving physician compensation may occur including fairness (specialists vs. primary care), effort, gender and racial equity, societal value, and the realization of the important psychological value of compensation.

• RVU-based compensation systems could lessen the academic productivity of an individual as well as the organization, so measures to reward academic effort should be included.

• The first step in managing a conflict of interest is full disclosure.

• “Conflict of Commitment” involves a situation in which an employee engages in an outside professional activity, paid or unpaid, that involves a commitment of time that may interfere, or appear to interfere, with fulfillment of the employee’s obligations to the University or academic health center.

• The physician leader has responsibilities to the patient and the health system. Conflicts may arise and should be resolved. One of the challenges to the physician leader is to ensure that it is clear in any given situation whether he or she is acting as the caregiver for a specific patient or as a healthcare system leader.

Physician Compensation

By far one of the greatest management challenges is physician faculty compensation. There are a wide range of physician compensation models. These include 100% salary model based on faculty rank. In this system the physician receives a pre-determined and fixed salary. This type of structure may lead to an increase in collaboration, teamwork, teaching and research as productivity is not a factor in the model. However, it provides little incentive for the physicians to bring in new patients, or to put more effort into building a practice. It may not be the best structure to encourage a long-lasting and growing practice. The second type is the
salary plus incentive model. This model guarantees a physician a minimum base salary which could then be supplemented with additional compensation in the form of a bonus based on productivity, outcomes, patient satisfaction, and work. In this model if the formula for the incentive is subjective there could be physician dissatisfaction. A third model is the equal shares model. In this model the revenue generated by the practice after expenses are paid are divided equally amongst the partners. However, this can be complicated as it does not take into consideration experience, unique skills, or productivity. This is rarely used in academic health centers. The changes that have accompanied health care reform and new payment structures have fundamentally changed the way academic physicians are compensated.

Reductions in NIH funding and physician reimbursement have been associated with less funding for faculty salaries prompting academic health centers to find other sources of funding including endowment, industry grants, part-time administrative positions for faculty and increasing the clinical productivity of the faculty. This has included the adoption of Relative Value Unit (RVU) based compensation systems for many physicians. Although originally intended as a measure of resource utilization the RVU has become synonymous with productivity. Employment contracts often utilize the work RVU (wRVU) as an adjusted measure of productivity and pay a salary with a bonus based on wRVU generation. This is often combined with a base salary. These are often referred to X, Y, Z compensation systems where in X is the base salary by academic rank, Y is an optional additional base pay component determined by administrative or other roles and is individually negotiated, and Z is an optional incentive that is based on productivity and other factors as defined by each institution. In this system, income is regarded as a management tool. If physicians are not doing enough work to cover their salaries, then they be subject to an adjustment in compensation based on the number of resource-based relative value units they generate. Many academic medical centers have moved toward a wRVU compensation model for physicians.

Gunderman and Hubbard address the ethics of physician compensation as well as the advantages and disadvantages of RVU systems. Although market forces are the primary determinant of physician compensation, ethical issues may occur including fairness (specialists vs primary care), effort, gender and racial equity, societal value, and the recognition of the important psychological value of compensation.1

One of the major perils of the wRVU models is that physicians might change their effort in line with compensation. If they are paid more for clinical work, then they may spend more time on patient care and less time on academic pursuits such as teaching, research and service. This could lessen the academic productivity of an individual as well as the organization. Hence, a system to reward academic productivity must be developed when such systems are put into place. As with other challenges to leadership, the key to success is fairness and transparency.

One of the pluses of RVU based compensation is that it removes a leader’s individual role in determining a faculty member’s compensation and the potential unconscious bias that may impact these decisions. In academic medicine, women physicians are compensated less than their male counterparts by academic rank and assignments. Such arrangements are unethical. It will remain to be seen if RVU compensation systems will correct the compensation disparity between men and women. Many are hopeful that it will. Yet, it may not, especially during the initial phases of the academic life of female faculty when competing family needs may decrease the effort they can generate. In setting compensation, leaders and organizations will be best served by a transparent and equitable compensation system.

**Conflict of Interest**

To maintain research integrity, it is important to limit sources of bias. Hence, Conflict of Interest has become a focus. A conflict of interest may arise anytime a professional opinion or judgment for a primary interest, for example in a research study, may be influenced by a secondary interest such as an industry sponsor. According to Kimbrough and Pawlik, “As opposed to ethical conflicts, where both sides of an argument may have equal claim to validity, in a conflict of interest, only the primary interest has claim to authority.” (Kimbrough and Pawlik, 2019, p. 93). We acknowledge that while industry funding is often desirable and needed for the conduct of research, the funding group should not be able to influence the results or interpretation of the results. There is empirical evidence that supports bias in industry-supported trials. Industry sponsored trials have been reported to have positive results in up to 85% of clinical reports as opposed to government funded trials which have positive results in only about 50% of reported studies.3
There will always be conflicts of interest in the conduct of biomedical research, whether basic, translational, or clinical. These conflicts can exist at the level of the individual investigator, the investigative team and even the institution. There may be professional or financial incentives that may bias judgment. The only way to completely avoid a conflict of interest is to not engage in research; rather, these potential conflicts should be identified and managed.

There are strong professional incentives for academic investigators and their teams to generate discovery-based research products. These research products lead to peer-reviewed publications in scholarly journals, successful grant applications, academic promotion, and professional prestige. These conflicts may even lead to the subtle bias of not publishing “negative” findings. Members of the research team should work in an environment of open sharing of research data, replications of experiments, careful archiving of all data, and independent reviews. Good scientists try to disprove their favorite hypotheses.

A financial conflict of interest can exist if the investigator is the named inventor of intellectual property or is a paid consultant or equity holder in the context of industry-sponsored research. These scenarios present the opportunity for bias at both the individual and even institutional level. In the context of human subject research, there is the potential for harm to patients. These inevitable conflicts of interest are best managed at an institutional level. Institutional Review Boards (IRB) are mandated to protect the rights and welfare of human subjects, but their scope of influence may not be adequate to manage various conflicts. Many institutions require an independent scientific peer review to gauge the worthiness of the hypothesis being tested on human subjects. Also, all research institutions should have a Conflict of Interest Research Committee composed of disinterested faculty and senior administrative staff to which faculty are encouraged to present all potential conflicts of interest and receive written recommendations on how to manage these conflicts in an open and ethical manner.

Full and transparent disclosure of all potential conflicts in grant proposals, publications, presentations, and informed consents goes a long way towards addressing these issues. Recommended industry relationships requiring disclosure are listed in Table 10-1. The Department of Health and Human Services addresses these issues in a clear manner in their published guidelines on Conflicts of Interest in Responsible Conduct of Research.

### TABLE 10-1: Industry Relationships Requiring Disclosure (100)

- Grants
- Consulting agreements
- Participation in speaker bureaus
- Honoraria
- Stocks, options and other ownership interests
- Position with a company including employment (full or part-time) or serving as an officer
- Participation on advisory boards or committees including scientific advisory boards and marketing panels
- Authorship of publications prepared by industry
- Expert witness consulting for the plaintiff or defense
- Other payments or financial relationships including consulting fees and royalty disbursements


Conflicts of interest are not limited to research and will also exist in clinical care as well. Physicians and surgeons may work with pharmaceutical or medical device companies on the development of new products and should be encouraged to do so. In this situation, the doctor may have a vested interest in having the company’s products added to the formulary or surgical supply inventory. Examples may include new chemotherapy drugs, antiseizure medication, specific types of joint implants, mesh to be used for abdominal wall reconstruction, and new laparoscopic or robotic equipment. At the institutional level, impartial physician and surgeon leadership and oversight of the formulary committee or new technology review committee is essential with a focus on effectiveness and value. Those faculty with a conflict of interest involving specific items should recuse themselves from discussion and decision-making process.
In addition to institutional oversight of industry conflicts of interest, the U.S. Government has introduced regulations designed to increase transparency of physician relationships with industry. Provisions of the 2010 Patient Protection and Affordable Care Act require that pharmaceutical and medical device companies report all payments or transfers of value to physicians or hospitals. The “Sunshine Act” requires reporting of payments as low as $100 per year or $10 per instance including gifts, entertainment, travel, and meals. In 2014, it was reported that the total payments to physicians was $6.6 billion. The Centers for Medicaid and Medicare Services maintains a website with free public access that provides access regarding payments to physicians and teaching hospitals.

**CASE EXAMPLE:** Failure to Disclose Conflict of Interest

In September of 2018, the Chief Medical Officer of Memorial Sloan Kettering Cancer Center (MSK), Dr. Jose Baselga, resigned after he admitted that he failed to disclose industry ties in 60% of nearly 180 papers which he had published between 2013 and 2018. During that time, Dr. Baselga received funding from a large company as well as several small biotech start-ups. He had ownership in some of the companies. He also sat on the Bristol Myers Squibb Board and it was estimated that he received $3.5 million in consulting fees between 2013 and 2017. When this information was revealed, although Dr. Baselga was well known nationally and internationally, he was asked to resign his position at Memorial Sloan Kettering. The executives of MSK realized that they had “no choice” but to ask him to step down. While this likely was done to save the reputation of MSK, it also was important to show other physicians and staff that MSK holds high standards based on strong ethical principles.

In addition to his work with pharma, Dr. Baselga was editor of a well-recognized cancer journal during this time. While he felt that his work with pharma did not affect his judgement in making editorial decisions, he had not disclosed his conflicts-of-interests. In December of 2018, the American Association for Cancer Research indicated that Dr. Baselga, at its request had resigned his post as one of two editors in chief of Cancer Discovery because he fell short of adhering to the high standards of the journal regarding conflict of interest disclosures expected by its leaders. Some of his omissions involved articles that were published in Cancer Discovery while he as an editor in chief. Parenthetically, in January 2019 AstraZeneca, the British-Swedish drug maker, announced that it had hired Dr. Baselga as its head of research and development in oncology, a newly created unit that reflects the company’s shift toward cancer treatments, one of the hottest areas in the drug industry.

This case is an example of how a major institution should respond to and handle the failure to report conflicts of interest. The ethical culture of the organization and its values as well as those of its leaders guide the response to these types of occurrences.

**Summary**

Funding for research may be received from various sources including hospital budgets, patient gifts, and philanthropy, research agencies, government agencies and industry. Researchers or clinicians may receive funding from industry to do clinical trials or assess and develop innovations. In these situations, clinicians should make it known that their research or clinical work is supported by industry. Individuals who do receive funding from industry to support a research trial are frequently lead or senior author for the project and hence will be involved with data analysis and manuscript preparation and requires full disclosure of their conflict as it is impractical to screen them from participation in these activities. Likewise, physicians who sit on company boards, or consult companies on pharmaceutical or medical device development should make that known and recuse themselves from leadership and involvement with institutional formulary or medical device committees involved with product selection for their hospital or health system.
Conflict of Commitment

“Conflict of Commitment” involves a situation in which an employee engages in an outside professional activity, paid or unpaid, that involves a commitment of time that may interfere, or appear to interfere, with fulfillment of the employee’s obligations to the University or academic health center, even if the outside activity is valuable to the University or contributes to the employee’s professional development and competence. Conflict of Commitment policies outline organizational guidelines for a faculty member’s disclosure and involvement with external activities. It behooves the leader to be aware of institutional conflict of commitment policies. Many universities have policies guiding conflict of commitment. We selected as an example from the website of the University of Iowa:

“The Conflict of Commitment policy applies to all full-time regular UI faculty members, including administrators with faculty appointments. Nothing in these rules shall be construed to require the disclosure of external activities for any period during which a faculty member is not on a University appointment (e.g., activities performed during an unpaid leave of absence, activities during the summer for academic year faculty) and requires regular full-time faculty use the following guidelines in determining whether to submit a written disclose of external activities. Outside Professional Activities (e.g., consulting with a non-university entity) that take place during a standard ‘business day’ (see definition) shall be disclosed in advance of initiating the work. Academic Activities shall be disclosed in advance only if the time required to conduct the activity interferes with the performance of assigned duties (e.g., faculty member will miss a class, regular office hours); or External Activities, which are not related to a faculty member’s professional expertise, shall be disclosed in advance of undertaking the activity only if engaging in the activity requires a substantial commitment of time or compromises, or has the appearance of compromising, a faculty member’s professional judgment in performing his or her University duties (e.g., teaching, research, business decision-making).”

As one can appreciate, it is not truly clear what the policy states in everyday language. In reality how does a faculty member meet the requirement? When do they need to notify the university? How much time can they commit to outside consulting? Does this include volunteer activities?

Most universities have similar policies. The enforcement of the policies is extremely variable. This may relate to the lack of clarity and practicality of the policy as well as applicability to faculty in the medical centers which have different compensation methods and levels of faculty responsibility. Therefore, it is important for a department or unit to have a process and system in place that can be used to facilitate resolution of potential conflicts of commitment. These may be tailored to the specific needs of the faculty but must be compatible with the institutional policies. As with other management challenges communication is key and necessitates engaging the faculty in policy development, informing the faculty of the provisions as well as establishing processes to review situations as they may evolve. Many times, the department or unit leader will be called upon to adjudicate these situations.

Conflicts of commitment occur more often than one realizes in academic medicine. They occur in several domains: 1) voluntary external professional service; 2) voluntary external clinical service (e.g., global surgery); 3) military service; and 4) external consulting (e.g., medical legal consultation, industry consultation including precepting physicians and surgeons in new procedures such as Transcutaneous Aortic Valve Replacement or robotic pancreaticoduodenectomy. The management of military service is usually a contractual obligation and is managed by institutional rules. The management of unpaid versus paid external activities are different, yet both can be facilitated by employing the strategies described for ethical decision-making.

The management of paid external consulting may be more straightforward. The key here is actually knowing if the faculty member has notified the institution of their absence. Most institutions have a paid external consulting policy that should be followed. Fortunately, most faculty are very forth coming and will notify the department and use personal or vacation time or unpaid leave if they are receiving compensation for the consulting work. For example, a physician who is serving as an expert
witness in medical legal litigation will have three components of that activity: case review, depositions, and testimony. Case reviews may be done during off hours or weekends. However, depositions and trial testimony may take place during regular work hours. Is it ethical for the physician to receive compensation for these activities and also institutional compensation or benefits? In these situations, it is most prudent to insist that vacation or unpaid leave be used by the faculty member who will be absent from work for these purposes.

The management of unpaid voluntary external professional service or clinical service is more complicated. The service being rendered has value to those being served. For example, in global surgery the impact of a surgeon volunteering to perform clinical surgery in an underserved country has value as it helps others. In addition, the physician providing the service receives professional value in providing the service. Is there value for the institution? In the global sense, yes, but should the physician receive institutional compensation for the time they are gone? Should the physician take unpaid leave or vacation to do this work? These are difficult issues. Applying, a framework for ethical decisions may help the leader find resolution.

CASE EXAMPLE: Voluntary Unpaid Service (Fictitious):

Dr. N is appointed to serve on the American Board of Surgery. She is the Chief of the Division of Acute Care Surgery (ACS) at a large public university hospital. She is a clinical professor. She is informed that her time commitment to the board will be 4–6 weeks per year depending on the number of certifying examinations in addition to the regular board meetings which occur in June, October, January, and April. This is a very prestigious appointment and will provide Dr. Jones with opportunities for career advancement as well as visibility for the university and the department of surgery.

The ACS Division has eight members. They take in-house call. Each faculty member is required to take six weeks of call in addition to a separate holiday schedule. The hospital pays the division $1000 per night to take call or $365,000 per year. The division has a break even budget after salaries and benefits. Salaries are paid using an RVU compensation system, supplemented by call pay and $400,000 per year from the university for teaching responsibilities. In addition to clinical responsibilities, the faculty have a major teaching requirement for the med 3 clerkship which include sixteen hours per week for small group sessions, lectures or simulations each week. Dr. Jones is also the trauma center director and is paid $100,000 annually for this role. Her total compensation is $375,000 per year. She is the highest paid faculty member in the division in which the average annual salary is $250,000.

The dilemma for Dr. N is how to meet her obligations to the university for her clinical, teaching, and administrative responsibilities while spending 4–6 weeks per year in a voluntary and prestigious board activity? There is value to the university in having a member serve in a prestigious role. There is personal professional value for Dr. N, as well. The difficult questions are as follows. Should she receive the same level of compensation as she did prior to accepting this role and what will be the source of the dollars to fund her compensation? How will the division cover her work assignments and how should the compensation change for participating faculty who will take on increased work in her absence?

There are multiple levels of conflict in this situation. First, Dr. N is the Division Chief and has budgetary authority. Hence, there is a direct conflict between her fiduciary authority and responsibility to achieve a balanced budget and her volunteer board activity. She has the direct authority to set her salary in discussion with the Chair, but it is likely that she will not make her RVU targets, meet her call requirements, teaching responsibilities or fulfill her administrative requirement as the trauma director while taking on the board duties. Where will the funding come from to pay her salary? In addition, separate to the financial reality, there is a conflict of commitment to the university to meet her faculty obligations. In many of these situations the faculty member maintains their current salary and the division picks up the additional work with some marginal increase in compensation for the other faculty. The end result may be guilty board member, a disgruntled group of surgeons, and a stressed clinical unit.
In this case the Chair interceded. Recognizing the institutional value of the board appointment, she provided department funds to cover the expense of compensation and benefits related to the time that Dr. N would be away for her board commitments. The Chair also recognized that in Dr. N’s absence, it would be necessary to have an associate trauma director to oversee that program. She negotiated an additional salary with the institution for this position and appointed an associate trauma director. This also created a potential succession plan within the department and institution if Dr. N should be recruited for other leadership positions at other institutions. The matter would have been more difficult to resolve without the use of discretionary funds.

The Physician and the Health System

Introduction

The physician leader is in a unique position to guide organizational policies regarding access to care, new procedure introduction, and response to organizational crises not only in specific institutions but in the overall health care arena in any society. In this role, the physician has a societal responsibility that takes priority over fiscal concerns.

The Dual Responsibilities of the Physician Leader

The care of patients does not occur in a vacuum. As such, decisions that are made for individual patients necessarily also affect society and the overall costs of care. Nevertheless, a central tenet of the ethical practice of medicine has been the importance of the physician being an advocate for her or his patient. In this manner, the patient’s benefit should be the central driver of decision-making rather than economic benefit of society or a healthcare system. Put another way, we should not encourage rationing at the bedside. If rationing decisions must be made in health care, they should not be made by the physician at the bedside of his or her individual patient, but on a system-wide basis.

In addition, ordering unnecessary tests or performing marginally indicated procedures to benefit the revenue of the health system or the physician is unethical. Although such practices have come under more scrutiny and physicians and hospitals are more accountable for costs, there are still drivers that may push physicians and surgeons to do unnecessary procedures to garner more income. This is another flaw of the RVU compensation system wherein a physician could perform a procedure or treatment with a high associated wRVU in order to increase productivity and compensation.

CASE EXAMPLE: Over-Utilization in a Fee-for-Service System

In the article entitled the Cost-Conundrum by Atul Gawande published May 25, 2009, he described that McAllen, Texas, a border town in the Rio Grande Valley with a metro population of 839,000, as one the most expensive U.S. health care markets. Somewhere between 1992, when the average cost per Medicare enrollee in McAllen was the same as the national average, and 2006, when McAllen’s costs were twice the national average, something changed. Gawande concluded that the high cost of health care in McAllen was the result of a culture of over-utilization in a fee-for-service system among healthcare providers. Health care economics has greatly changed since then as the Affordable Care Act was signed into law in 2010. Gawande revisited McAllen six years later when he published Overkill in 2015. He discovered that McAllen had changed. From 2009 to 2012, costs had decreased by an average of $3,000 per Medicare recipient and there had been a 10% reduction in hospital admissions, and a 40% reduction in spending for both home health services and ambulance rides. He acknowledged that changes in physician behavior had initially occurred due to increased scrutiny and the threat of more negative publicity and lawsuits. However, he credited primary care and the debut of the accountable care organization as the force that maintained this change.
In the role of a leader, a physician may have dual responsibilities. Without question, in his or her capacity as a physician taking care of an individual patient, the patient's benefit should be the primary focus. However, the physician-leader also has a clear responsibility to the healthcare system. Without attention to the long-term financial viability of the healthcare system, the physician leader will be shirking his or her responsibilities. In this fashion, the physician leader has dual responsibilities to both individual patients and to the healthcare system. The following two paragraphs will exemplify these dual responsibilities.

It is important for physician leaders to recognize their multiple roles and be clear about the role in which they are making decisions or recommendations at that moment. For example, if the chief of surgery has been on call for the emergency room and has admitted a 40-year-old patient without insurance for a fourth episode of diverticulitis in the last six months. He or she may choose to treat the patient with antibiotics, whereas he or she may choose to treat a patient with insurance with an operation. Although a non-operative approach would probably take care of this episode, it does not take into consideration that eventually the patient will have another episode requiring hospitalization. Whether the patient has insurance or not cannot be relevant to the decision about whether the patient should have emergency surgery. In this situation, the chief of surgery role is irrelevant. The patient is interacting with this surgeon as he or she would with any other physician. As such, the patient should reasonably expect that recommendations are going to be made solely on the basis of benefit to the patient.

In contrast, if the chief of surgery is placed on a committee to negotiate which insurance plans will be accepted in the healthcare system, in this situation, he or she should be making decisions based on what will ensure the long term viability of the system. Such decisions should not ignore patient welfare. There should not be even a single identifiable patient who will be placed at risk based on the decisions that are made.

One of the challenges for the physician leader is to ensure that it is clear in any given situation whether he or she is acting as the caregiver for a specific patient or as a healthcare system leader. The physician leader may be put in awkward situations where there is discord between her or his patient and the health system. The physician is an advocate for the patient and may need to help resolve the complaint in the best interest of her or his patient. It is also important that colleagues appreciate the differences and the manner in which it is necessary to shift the focus of one’s attention from the individual patient to the system.

**Introduction of New Surgical Techniques and Technology**

Some of the most difficult challenges for the physician leader surround the introduction of new surgical techniques or technologies. It is well-known that in the contemporary practice of surgery, many patients assume that what is new is automatically improved. This widespread acceptance that new things are better, has been a major driver of marketing efforts throughout healthcare. Specifically, when a hospital or healthcare system adopts a new technique early, there is the potential benefit of gaining market share before other surgeons or institutions adopt the new approach. The challenge is often to know when to allow the marketing for a new procedure to suggest that it is actually better than the traditional operation. Although there is no legal necessity to wait for actual evidence of patient benefit before claiming in marketing that the new approach is better, there is a clear ethical imperative to wait for such evidence. For example, surgeons and other physician leaders should both be clear that new procedures should not be marketed to patients as better without good evidence that patients have more favorable outcomes. How much data is necessary before making claims of improvement must be determined on an individual basis, but attention to the ethical imperative to avoid overpromising the benefits of new procedures is clear.
CASE EXAMPLE: Robotic Inguinal Hernia Repair (Fictitious)

A community hospital affiliated with a large academic health system in California acquired a robotic surgical system for urologic and gynecologic procedures. The robot is only used two days per week for these procedures. The hospital administration meets with the department of surgery to determine if there are other service lines that may be able to use the equipment. The general surgery group has a large practice in inguinal hernia repair. They begin to develop a program to offer robotic procedures rather than laparoscopic or open inguinal hernia repair. In order to be able to use the robot they first each need to complete 25 proctored cases. They each complete the required 25 cases doing robotic cholecystectomy. The inguinal hernia program is developed and begins to increase in volume. The surgeons also begin offer robotic cholecystectomy as a standard procedure. Although reimbursement for these operations is the same as open or laparoscopic approaches, the surgeons begin to increase the robotic volume. The administration wishes to advertise the robotic service line to increase volume. At this point, there is no evidence that the robotic procedure is better than traditional approaches. Should the hospital advertise this new technology? If so, should they make any comments about the benefits of the robotic procedures. From an ethical point of view the hospital should not advertise any potential benefit of the robotic procedure as there is no information supporting this contention. In this setting, one opportunity would be to develop a clinical trial or join a multicenter prospective trial comparing the efficacy of the robotic approach to other techniques. This would help the organization meet its obligation as part of an academic health system and better serve the community.

Not only must physician leaders be concerned that new procedures are being strongly recommended to patients as better too soon, they must also be certain that patients have the opportunity to hear about the best treatment options even when that option is not available in the healthcare system. For example, if there were no surgeons performing laparoscopic adrenalectomies at a hospital, it is still the responsibility of the physician leaders to ensure that patients are being informed of that option. In this situation, the potential benefit to the healthcare system of keeping a patient in the system for surgery is outweighed by the importance of patients hearing all the good options in order for informed consent to be valid.

Summary

Although the important principles of beneficence, nonmaleficence, respect for patient autonomy, and justice should not be ignored by the physician leader, the actual recommendations made will be dependent on whether the physician leader is acting in the capacity of a patient’s doctor or as a healthcare leader. Physician leaders must be clear to themselves and their co-workers in which capacity they are acting when making various recommendations.

References

Chapter 1: The Foundations and Principles of Ethics

Key Points

• The term ethics refers to the philosophical study of the concepts of moral right and wrong and moral good and bad and any system or code of moral rules, principles or values.
• The history of ethics highlights its importance to every period in the history of humankind and in every culture and religion.
• Bioethics is generally more related to theoretical ethical issues and concepts surrounding all biomedical technologies, such as cloning, stem cell therapy, xenotransplantation, and the use of animals in research.
• Medical Ethics tends to be more specific and focuses on the medical treatments and needs of human individuals.
• Surgical Ethics is distinct from bioethics and medical ethics. It recognizes the rights of surgical patients, and the fact that the dyadic relationship between surgeon and patient is based on the role of authority of the surgeon due to his or her expertise and competence and the power of the patient to allow the surgeon to act on his or her body. Surgical ethics has five unique characteristics: rescue, proximity, ordeal, aftermath and presence.

Chapter 2: Definition of Leaders and Followers

Key Points

• Leadership is the exercise of influence and power in a group context in order to achieve common goals.
• The definition of leadership is incomplete without distinguishing between leading and following.
• Leaders are sometimes followers and followers are sometimes leaders depending on the context.
• The unique features of medical training which emphasize duty and moral obligations to patients and society prepare a physician for ethical leadership.
• Patient care is a moral practice and the physician's role as a moral fiduciary is at the core of medical ethics. Hence, physicians have unique attributes that prepare them for ethical leadership.

Chapter 3: The Construct of Ethical Leadership

Key Points

• Surgery is a moral practice and every surgeon should be considered a moral fiduciary agent.
• A surgeon in a leadership position needs to be a promoter of Ethics in the organization or institution.
• Ethics provides a framework for three aspects of the surgical practice: a) the virtues and obligations within the dyadic relationship between patient and surgeon, b) the surgeon's professional duties and conduct and c) the surgeon's responsibility towards society.
• Ethical leadership is essential for patients, surgeons and society.
• The four ethical principles; vision together with values, voice, and virtue; are at the core of ethical leadership.

Chapter 4: The Challenges to an Ethical Leadership in Academic Medicine

Key Points

• The challenges of leadership include the management of power, privilege, and information, and attainment of equipoise in consistent decision-making and while balancing loyalties and responsibilities.
• Power may be classified as formal (legitimate, coercive, and reward based) and personal (referent and expert). The crucial decision for the leader is to decide what types of power he or she should use, in what situations, and for what purposes.
• Becoming an effective leader requires one to consider and reflect on material privilege and privileged identity and how these relate to leadership and are viewed by and effect followers.
• As a result of involvement in decision-making, leaders have more access to information than do others in an organization. The leader is a fiduciary of information and must consider when and how much information to share.
• An effective leader makes decisions in a consistent and fair manner devoid of favoritism and bias even under conditions of uncertainty.
• An effective leader is challenged to equitably manage competing loyalties.
• A leader in Academic Medicine is responsible to many stakeholders including the public, the organization, faculty, staff and learners. He or she is responsible for establishing processes that enhance and maintain a “psychologically” safe environment for employees, faculty, learners and patients, manage scientific misconduct, ensure compliance with Medicare billing and HIPAA regulations and other healthcare regulations and assure appropriate credentialing for privileges.
Chapter 5: Establishing an Ethical Culture: The Importance of Ethical Decision-Making

**Key Points**

- Fairness in the management of the tensions created by the dynamic relationship between the leader and his or her followers yields a successful unit by all measures and an engaged and satisfied group of faculty and staff.
- Aligning individual faculty expectations with organizational goals is an essential priority for an effective leader.
- Management of academic units is enhanced by establishing and promoting an ethical culture which may include establishing a code of conduct.
- Ethical decision-making strengthens an ethical culture in the organization:
  - The search for guidance in ethical decision-making for the physician leader should be an ongoing one.
  - There is no absolute roadmap of how to make ethical decisions nor is there a flow chart to clearly identify how to avoid making decisions that may not meet the ethical expectations of others.
  - A framework for making ethical decisions should not be thought of as a full-blown ethical theory, but rather as a means of using multiple ethical theories and ethical principles along with additional considerations in deciding what is the optimal choice.
  - Ethical decision-making is important for all decisions rather than only for those that narrowly fit within a specific category.

Chapter 6: Breaches of Ethical Principles: Frequency, Examples and Management

**Key Points**

- No matter how mature and effective the ethical leadership and culture of your organization, there will always be the risk of ethical breaches by individuals in the midst of an organization. They will never be eliminated.
- Ethical breaches may involve clinical care, billing compliance, personnel interactions, academic integrity, research, and education.
- Although the number of severe disciplinary actions involving physicians is low averaging about 1/1000 physicians, it is similar to the annual incidence of breast cancer and far greater than the incidence of HIV.
- Despite clear patterns, no factors provide readily observable red flags, making prevention of ethical breaches difficult.
- It behooves the leader and her or his organization to prepare and to have a system in place to recognize and manage incidents involving ethical issues in a timely fashion and with full transparency.
- Administrative inaction can be viewed as breaking our social contract with the public and our internal community.
Chapter 7: Management of Ethical Issues in Human Subjects and Basic Science Research

Key Points

• Each principal investigator (PI) and co-investigator (Co-I) plays an important triple role: each one must be an excellent researcher, a strong leader, and an ethics advocate.

• The Common Rule, established in 1981, is the fundamental standard of Ethics to which any government-funded research in the United States is held; nearly all U.S. academic institutions hold their researchers to these statements of rights regardless of funding source.

• A leader should support education on best research practices and systems to monitor training. One such computer-based learning tool has been developed by the Collaborative Institutional Training Initiative (CITI); content that includes nearly twenty-four subject areas.

• To ensure subject rights, it is the investigator's responsibility to make sure that subjects are well informed, and all questions are answered.

• The seven requirements for ethical clinical research include Value, Validity, Fair Subject Selection, Favorable Risk Benefit Ratio, Independent Review, Informed Consent, and Respect for Enrolled Subjects.

Chapter 8: Ethical Issues in Data Collection, Analysis and Publication

Key Points

• The definitions of research misconduct including Fabrication, Falsification, Plagiarism are clear, but detection is difficult.

• Although the Common Rule specifies annual reviews of research projects to detect research related events, patient complaints, and protocol deviations, these will likely be unable to detect data falsification.

• The Federal definition of Research Misconduct is discussed as well as the origins of the Office of Research Integrity. A case example of research fraud is used to show how difficult it can be to detect as well as the unfortunate impact on the unknowing public and patients.

• The issues concerning author order and that of dual primary or senior authors in discussed.

• Committee on Publication Ethics (COPE) provides guidelines to authors, institutions, and journals to address issues of authorship should they arise.
Chapter 9: Ethical Issues Involving the Trainee: Mentoring, Resident Autonomy and Research

**Key Points**

- The role of the mentor is a fiduciary one and its foundations lie on loyalty and trust.
- A mentor is not a synonym of a supervisor, instructor, faculty, trainer, coach, or boss.
- An academic leader in the surgical field has an ethical duty to provide an environment which supports nurturing, developing, and enhancing mentor-mentee relationships.
- A reliable mentor hones the acquisition of knowledge, expertise, and judgment in mentees to advance and progress not only in the professional but also the personal life.

Chapter 10: Ethical Issues Involving Faculty

**Key Points**

- Although market forces are the primary determinant of physician compensation, ethical issues involving physician compensation may occur including fairness (specialists vs. primary care), effort, gender and racial equity, societal value, and the realization of the important psychological value of compensation.
- RVU-based compensation systems could lessen the academic productivity of an individual as well as the organization, so measures to reward academic effort should be included.
- The first step in managing a conflict of interest is full disclosure.
- “Conflict of Commitment” involves a situation in which an employee engages in an outside professional activity, paid or unpaid, that involves a commitment of time that may interfere, or appear to interfere, with fulfillment of the employee’s obligations to the University or academic health center.
- The physician leader has responsibilities to the patient and the health system. Conflicts may arise and should be resolved. One of the challenges to the physician leader is to ensure that it is clear in any given situation whether he or she is acting as the caregiver for a specific patient or as a healthcare system leader.
Evaluation of one’s leadership skills, including those in the ethical dimension may be of interest to some. The list below provides several excellent resources.

1. Leadership Instruments Library (LIL) for Graduate Research at the James Madison University.


   The LIL was the brainchild of Dr. Karen Ford and staff at the School for Strategic Leadership Studies (SSLS) at James Madison University (JMU) in Harrisonburg Virginia, including Dr. Margaret Sloan, Dr. Dary Erwin, Dr. Adam Vanhove, and Brooke Rhodes. SSLS wishes to thank Dr. Sam Nickels for leading and writing the first draft of this project. He was assisted in the first edition by JMU Honors Program students carrying out an independent study: Jamie Simpkins, Elijah Phillips, and Karlie Lorenz.

   This library consists of over 100 instruments that are related to individual and organizational measures of leadership. The above link is to a document that provides information on how to use the site. Many of the instruments may be obtained with no charge.

2. Ethical Leadership at work (ELW) questionnaire

   The link below is to an article describing validation of a multidimensional instrument. This is from the James Madison University resource.


   The link below is to the full article

3. Leader Attributes Inventory
This available at the LIL site at James Madison University. This instrument Measures the degree to which individuals possess each of 37 attributes (characteristics, knowledge, skills, and values possessed by individuals) that predispose successful leadership performance as a leader in vocational education. The Leader Attributes Inventory (LAI) instrument comes in a Self-Rating Form and an Observer-Rating Form. Although, it was developed in 1990 it has been used in many studies. The site indicates that they downloaded the instrument at no cost at the links below.
https://eric.ed.gov/?id=ED374337

4. Development and validity of the Ethical Leadership Questionnaire
This study had five objectives: explain the initial steps that led to the construction of the Ethical Leadership Questionnaire (ELQ); analyze the items and verify the ELQ reliability using item response theory (IRT); examine its factorial structure with a confirmatory factor analysis (CFA) and an exploratory structural equation modeling (ESEM) approach; test the item bias of the ELQ; assess the relation between the ELQ dimensions and ethical sensitivity. The paper aims to discuss these issues.
The link below is to the paper

5. Ethical leadership at work questionnaire (ELW): Development and validation of a multidimensional measure
This paper describes the development and validation of the multi-dimensional Ethical Leadership at Work (ELW) questionnaire. Based on theory, interviews and a student sample, we developed seven ethical leader behaviors (fairness, integrity, ethical guidance, people orientation, power sharing, role clarification, and concern for sustainability).
The link below is to the paper.

6. Ethical Leadership Toolkit–Ethical Leadership Self-Assessment Tool–U.S. Department of Veterans Affairs
This self-assessment tool is designed to be used in conjunction with the ethical leadership video and primer, Ethical Leadership: Fostering an Ethical Environment & Culture. The tool may be completed as part of a self-assessment or 360 degree assessment.
https://www.ethics.va.gov/ELSA.pdf

7. IntegratedEthics
“Executive Summary Ethical Leadership: Fostering an Ethical Environment & Culture establishes VA guidance for ethical leadership, one of the three core functions of IntegratedEthics. This primer was designed to supplement the IntegratedEthics training video on the same topic. Targeted to VA leaders at the executive and mid-manager levels (as defined in VA’s High-Performance Development Model), it offers practical suggestions for how leaders can support ethical practices in their organizations. It was designed to be read initially in its entirety. Subsequently, it can serve as a useful reference when leaders wish to refresh their memories or to answer specific questions.”
https://www.ethics.va.gov/elprimer.pdf
8. Measuring Ethical Culture

The GoodCorporation provides excellent information on the ethical culture health check.

“Recognised worldwide in the field of corporate responsibility and business ethics, GoodCorporation has nearly twenty years’ experience of checking and measuring corporate behaviour, including anti-corruption practices. We have over 100 clients, including FTSE 100 and CAC40 companies and have conducted more than 600 assessments in over 70 countries. Data gathered from our assessments is used to benchmark business behaviour. This enables GoodCorporation to identify those management practices that are successfully embedded and highlight weaknesses that might leave an organisation exposed to reputational damage. We support our clients through assessment, certification, training and advice. We also provide opportunities to share best practice and thought leadership through our Business Ethics Debate Series at the House of Lords.”


This is an excellent resource and provides several examples of tools to assess your ethical leadership potential and opportunities as well as to measure the ethical climate of your organization.
Chapter 1: The Foundations and Principles of Ethics


Chapter 3: The Construct of Ethical Leadership
Chapter 4: The Challenges to an Ethical Leadership in Academic Medicine


Chapter 5: Establishing an Ethical Culture: The Importance of Ethical Decision-Making

Chapter 6: Breaches of Ethical Principles: Frequency, Examples and Management


2. Federation of State Medical Boards. U.S. medical regulatory trends and actions. Dallas, TX; 2014.


APPENDIX THREE: Master Reference List


Chapter 7: Management of Ethical Issues in Human Subjects and Basic Science Research

Chapter 8: Ethical Issues in Data Collection, Analysis and Publication


Chapter 9: Ethical Issues Involving the Trainee: Mentoring, Resident Autonomy and Research


**Chapter 10: Ethical Issues Involving Faculty**


