***Chapter Two***

**Ethical Approaches to Bioethics**

**Introduction**

 The term “moral” is derived from the Latin word *mos* or *moralis* meaning custom and the term “value” denotes good, benefit, or truth in cognition. The capacity to reason and think rationally about the good or even the irrational is one major force motivating humanity to establish a morally and ethically-based society. Thus, a moral society attempts to examine individual human character, human actions, and legal institutions, in order to shape a set of beliefs and values that will obtain the most good for the greatest number of persons. The guiding values of a moral society have been characterized as absolute, objective, and eternal.

 The word “ethics,” often used interchangeably with morals, is derived from the Greek word *ethike*, meaning habit, action, or character. Ethics is conceptualized as the branch of philosophy that deals with moral aspects of human behavior and is the study of how decisions are made, what is right and wrong, or what is better or worse. Ethical theory is the process used to define and justify how specific ethical decisions are made because terms like morality, ethics, and values are difficult to define objectively or scientifically.

 Medical ethics refers to the application of general and fundamental ethical principles to clinical practice situations including biomedical research. As described in Chapter 3, there are obviously overlapping principles in both research bioethics and medical ethics. We begin this chapter by first summarizing some of the moral/ethical principles that have been applied to bioethics and medical ethics. Those interested in a more comprehensive study of these principles should read from the following books (Beauchamp and Walters, 1999; Bulger et al., 2002; McGee, 2003).

 **Classical Ethical Theories**

 Before describing modern theories of ethics, it is important to highlight one continuing controversy underlying many ethical theories. Plato was one of the earliest philosophers to argue that the validity of moral cognition is absolute and objective. Plato believed that ethical laws and principles should be universal and apply to all cultures at all times. Secular “rationalist” philosophers, such as Socrates and Immanuel Kant, argued that people should primarily rely on intellect when distinguishing right from wrong. In contrast, “sentimentalists”, like David Hume, believed that emotions, such as empathy, should guide moral decisions. Interestingly, brain-scanning technology support the idea that both rationality and emotion influence moral choices (Shenhav and Greene, 2010). The moral brain is seen as a camera that comes with manufactured presets, such as “portrait” or “landscape,” along with a manual mode that requires photographers to make adjustments on their own. The presets are emotional responses, which are influenced by biological makeup and social experiences. The manual mode is both time-consuming and cumbersome and represents behavioral responses and rationality.

These approaches to ethical theory have permeated bioethics as well. In their classic work, Beauchamp and Childress divided bioethical theory into two major ethical schools: a deontological approach and a utilitarian approach. Deontology is rooted in the Latin word *deon* which means ‘duty’, and maintains that the concept of duty is independent of the concept of good, and that the correct actions are not necessarily determined by goodness. In this theory, one has to determine what is right or wrong by asking whether an act or sets of action would likely produce the greatest benefit to a society. Deontological theories of ethics state that an act is considered proper and good if it fulfills basic requirements of ethical values, without regard to the expected or anticipated consequences. Many religions are founded on this ethical principle. Immanuel Kant is credited for developing a secular modern approach to deontology. He emphasized that there are ethical values that dictate actions categorically without compromise. Kant asserted that ethical law is not determined by experience but is an imperative - objective, absolute, and unrestricted. Kant believes that generally the consequences of actions should not be considered. Rather, emphasis should be placed on moral rules of duty, autonomy, justice, and kind acts.

The utilitarian approach, in contrast, emphasizes that actions are morally acceptable when they lead to the greatest possible **balance** of good and harmful consequences. In other words, actions should promote maximum benefits with minimum harm. Utilitarian ethics defines a specific goal and a specific action to achieve that goal. The utilitarian approach has its origins in the writings of David Hume, Jeremy Bentham, and John Stuart Mill, who believed that consideration of the consequences of any actions are vital in any decision-making process. Mill emphasizes this in his two fundamental principles of utilitarianism:

The first is the principle of utility. Actions are moral and right in proportion to their ability to promote happiness. It is necessary to determine the “goodness” and “badness” of a set of consequences. Specifically, Mill’s theory advocates that morally right actions are determined by the non-moral value produced by their performance. Non-moral values are general characteristics of human striving and include pleasure, friendship, knowledge, and health.

Mill’s second principle is psychological and intrinsic to human nature. Mill believed that most people have a basic desire for unity and harmony with other people in order to produce the greatest possible balance of value over disvalue for all individuals. According to Mill and his proponents, actions are judged right or wrong solely by their consequences. Right actions are those that produce the greatest balance of happiness over unhappiness. Since each person's happiness is equally important, a good action is one that brings the most beneficial results to the most people.

 Kant’s ethical deontological philosophy has been challenged on several levels by those who favor a utilitarian approach to ethics. First, it is difficult to determine who decides on absolute values and how to implement them. Second, Kant’s theory completely disregards the consequences of actions. Finally, the deontological theory does not provide a mechanism to decide between two or more universal values that are in conflict.

 In response to these challenges, various neo-Kantian theories have been proposed. Some ethicists combine deontology with utilitarianism (see below) and emphasize the need to evaluate both absolute and universal values to structure values that moral cultures can follow. Other ethicists, such as John Rawls, author of “A Theory of Justice,” (Rawls, 1999) emphasize the principles of honesty, equality, and social justice within a deontological framework. In this view, social justice is the highest ethical value and different characteristics of individual peoples are ignored. Rawls objected to the principle of utilitarianism by proposing that maximizing benefits can violate basic individual liberties and rights that should be guaranteed by social justice. According to Rawls, a practice is just if it is in accordance with a particular set of morally defensible principles of justice that the participants agree on for a specific situation. For Rawls, a social contract is a hypothetical not a historical contract. He proposed that each individual in a society be permitted the maximum amount of equal basic liberty compatible with a similar liberty for others. Thus, once equal basic liberty is assured, selected inequalities in social benefits would be permitted only if they benefit everyone and only if everyone has an equal opportunity to receive those benefits.

 The utilitarian approach to ethics has also been challenged. First, in many situations it is difficult to weigh the expected benefit if varying and conflicting actions are occurring simultaneously. Second, utilitarianism can lack ethical consistency in decision-making processes because it changes with different expected outcomes. Third, benefiting the majority may create serious harm to the remaining minority and lead to unjust social distributions of benefits. Finally, utilitarianism is based on the premise that ethical acts themselves have no intrinsic value and outcome and consequence are the prime determinants of action. Hence, some actions could be ethically wrong but still justified because their outcome produces the desired benefit.

 Beauchamp and Childress summarize the differences in these two schools quite clearly. “The utilitarian holds that actions are determined to be right or wrong by only one of their features -- their consequences --; while the deontologist contends that even if this feature sometimes determines the rightness and wrongness of acts, it does not always do so” (Beauchamp and Childress, 1979).

 In the last fifty years, other ethical theories have been developed in an attempt to create a school of ethics within the context of both bioethics and medical ethics (see Moore, 2012 for a review). None of these theories are universally accepted.

 **Steps in Resolving Ethical Dilemmas**

There is no consensus among modern ethicists which of the above theories is best applied to resolve issues of bioethics or medical ethics. However, common steps in analyzing bioethical dilemmas include:

* *Identifying and recognizing the specific ethical issues for any case.*
* *Identifying the key facts*, *important* *definitions, and what remains to be discovered in a particular case*.
* *Identifying the stakeholders.*  Are the stakeholders in a case the research scientists, patients, or commercial companies supporting research that will generate profits?
* *Identifying those ethical principles or guidelines that best apply to the case.* In cases where there are conflicting principles, how would you establish a hierarchy?
* *Evaluating how a course of action will impact the specific issues and their impact on other related social or biomedical issues.*
* *Evaluating how would your chosen course of action impact future cases.*

**Fundamental Guidelines in Bioethics and Medical Ethics**

 Ethics and science differ in several aspects. First, specific conclusions and future directions in the pursuit of scientific knowledge are based on objective observations through the process of experimentation. In contrast, bioethical or medical ethical questions cannot be resolve by experimentation. The result is that many ethical theories can be employed to deal constructively with moral disagreements and no single set of ethical considerations will prove consistently reliable as a means of ending disagreements and controversy.

 In classical medical ethics, there are four basic guidelines considered in evaluating ethical dilemmas (Bulger et al., 2002):

* *Autonomy, Respect* *for Persons, or Self-determination* is the right of the individual to determine his/her own destiny. Respect for persons implies that everyone has intrinsic value and incorporates two ethical convictions: 1) a right to personal liberty, i.e., they are autonomous, and 2) a right to be properly informed. The granting of autonomy implies that society recognizes the free choice of each person even if that choice seems inappropriate or even life-endangering. The second is that those individuals who do not have the resources, education, or capacity for self-determination should be protected. The principle of autonomy and respect also assumes that 1) the individual’s right to act should be mediated by reason and not desire and 2) social and political control over individual action requires the prevention of harm to other individuals affected by those actions.

For autonomy to be realized a patient must have the capacity for understanding the situation with its risks, benefits, and alternatives and of reasoning through to a decision that appreciates the consequences. It is a tremendous responsibility for caregivers to educate patients adequately. How much information is material and sufficient? While autonomy is highly valued in the United States, it is often difficult to be confident that the physician has provided all the information necessary for the patient to make complex medical decisions. Even the most educated patient may not have a sufficient understanding of all medical issues and concerns to weigh all risks and benefits correctly. In addition, autonomy has to be modified when dealing with mentally challenged individuals, children, comatose patients, or even those who are highly traumatized who are temporarily or permanently not competent to make decisions for themselves and hence do not have autonomy.

* *Beneficence* is the capacity to do good or what is best for the patient. Therapeutic privilege also comes under beneficence: the physician’s subjective determination of what seems to be in the best interests of the patient is a critical component of beneficence which may preclude providing fully informed consent to avoid causing anxiety or depression.
* *Non-maleficence*. While incorporated in the concept of Beneficence, this is often considered asa separate guideline. Non-maleficence operationalizes the Hippocratic doctrine to strive to “do no harm,” and has three sub-themes: not to inflict evil or harm; to prevent evil or harm; and to remove evil or harmful forces or conditions in society.
* *Justice* demands fairness in distribution of resources (including accessibility and finances) where the benefits and the burdens (risks) are to be shared equally. Justice requires the division of rights and assets in an equitable and appropriate manner. Injustice occurs when some benefit is denied or some burden is imposed without reason or acceptable justification. An historical approach of new biotechnologies reveals that often initial scientific discoveries are highly expensive. The first sequencing of the human genome at the turn of the 21st century cost close to one billion dollars. Fifteen years later, the cost to sequence a human genome is less than $1000 and it is estimated that within the next five years, the costs will go down to less than $100. On the other hand, the costs of in vitro fertilization technologies (IVF) continues to remain quite high averaging between $25,000=$50,000 for one round of IVF.

Rawls's Theory of Justice (1999) details two fundamental principles of justice. The first principle guarantees the right of each person to have the most extensive basic liberty compatible with the liberty of others. The second principle states that social and economic positions are to be (a) to everyone's advantage and (b) open to all.

**Hierarch of Bioethical Guidelines**

One of the major challenges in presenting bioethical guidelines is how to establish a hierarchy of which guideline should take precedent when a situation elicits conflicting guidelines. A classic example relates to end of life issues. Does the autonomy of a dying patient’s desire to engage in euthanasia trump over the guideline of non-maleficence? Here beneficence conflicts with autonomy. How to establish hierarchy of these guidelines is often a function of culture. In the United States, autonomy is viewed by many bioethicists as the most important guideline.

A second example relates to gene editing. How should one view the decisions of parents who want to apply gene editing to their embryo for non-medical applications? Do parents have the autonomous right to genetically alter the hair color of their child? In some situations, often introducing new biotechnologies into a clinical situation is extremely expensive and limits who can partake of these new biotechnologies. Gestational surrogacy is an example of an expensive technology in the United States costing anywhere between $50,000 - $100,000. However, couples can recruit gestational surrogates from developing countries such as India for less than $1500. The ethical problem associated with foreign surrogates is that they are subjected to greater abuse and misuse (conflicting with the guidelines of non-maleficence and justice).

**What is a disease?**

 Any discussion of bioethics in the 21st century has to focus on defining what a human disease means in scientific and social terms. A basic assumption within modern medicine is that health is the absence of disease (Scadding, 1988), and illness is the patient’s personal experience of disease. The World Health Organization (WHO) defines health as a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity. Yet, these definitions are clearly neither precise nor scientific. One problem is that it is unclear if health, illness, and disease are purely biological issues. In fact, purely biological approaches to chronic illness often do not produce the anticipated benefits. It is now well accepted that psychosocial factors play a major part not only in the experience of illness, but also in the development of disease (Engel, 1977). This has led other scholars to propose a ‘reverse view’ concept of disease, that the process doesn’t start with dysfunction as abnormal function, but with the patient’s experience of illness as ‘action failure’ (Fulford, 1999). Immune/health status is now a form of *habitus* or personal “capital” that increasingly is used in society to establish a general kind of fitness or even moral virtue.

 Human beings in general tend to be prone to black-and-white thinking. It can be very difficult to see something—especially something like autism—in shades of gray. Autism (or Autism spectrum disorder) is now described as a spectrum of conditions rather than a disease state that can cause significant social, communication and behavioral challenges in an individual. Interestingly, famous individuals, such as Albert Einstein, Darryl Hannah and Wolfgang Mozart have been described as exhibiting symptoms of Autism spectrum disorder. Would you describe their alleged symptoms as a “disease” or as an “asset” that enabled them to make significant contributions to society?

Culture can have dramatic effects on the categorization of an alleged disease or disorder. In the first half of the 20th century, many physicians viewed homosexuality as an endocrine disturbance requiring hormonal treatments or as a psychiatric disorder that could be treated using conditioning or psychotherapeutic methodologies. At that time it was classified as psychological pathology or abnormality. Yet in 1974, homosexuality was officially de-pathologized by the American Psychiatric Association when they removed it from their list of disease states. In 2015, the Supreme Court issued a legal and moral decision that the Constitution guarantees a right to same-sex marriage.

 Today, our definition of disease still remains imprecise but nonetheless important. Defining a condition as a disease is associated with decisions concerning whether or not it is important to allocate research and medical funds to correct or treat this condition. Defining a disease also has an impact on the system of health insurance. Medical insurance coverage requires that a code specifying a medical condition, symptom, or procedure be entered. Without a code, there would be no reimbursement.

 Many conditions that heretofore have been considered within normal human variation, such as baldness or short stature, have now become medical conditions. In 2004, Medicare discarded its declaration that obesity is not a disease. This policy change allowed millions of overweight Americans to make medical claims for treatments such as bariatric (stomach) surgery and prescription diet regimens. Likewise, baldness and short stature are classified as medical conditions because medical treatments for them now exist that healthcare professional administer and which are highly profitable.

Finally, defining a disease state is vital for major pharmaceutical companies in their analysis of whether developing treatments for a particular disease are going to be marketable and economically profitable. Successful examples would include treatment for infertility or sexual problems (e.g., Viagra for male erectile dysfunction and “pink Viagra” to treat hypoactive sexual desire disorder in women). Interestingly, Pink Viagra is the only FDA approved drug for women experiencing sexual dysfunction whereas there are over 25 FDA drugs approved for male erective dysfunction. Pharmaceutical companies also look for new marketing opportunities to prescribe already tested and approved drugs for new untested and “off-label” uses. Many are concerned about the influence of the Internet as well as direct to consumer advertising on medical decision-making. The examples above illustrate how the perceived medical needs of the public impact well beyond the classical doctor - patient relationship.

***Late Onset Diseases and Genetic Testing?***

How should ethicists deal with pre-natal testing for diseases that have late-in-life onset, such as Alzheimer’s disease, breast cancer, or Huntington’s disease? Would a Woodie Guthrie, one of the most celebrated and influential folk singer-songwriters of the twentieth century, be born today if his mother terminated the pregnancy because of genetic testing? Would his parents, who carried the Huntington’s disease gene, bear a child with the known risk that can be established by genetic screening? Many have argued that certain individuals born with genetic or congenital conditions that constrain their lives in challenging ways are driven to be more productive in society, considerably as a result of their disabilities.

 Ethical and definitional quandaries are abound. For example, how do we define a person who is either a carrier for a genetic disease or has a genetic predisposition to a disease? As one example, everyone agrees that government funds should be allocated to enhance breast cancer diagnosis and treatment. But is a 16-year old teenage girl with a genetic predisposition to a

breast cancer already considered ill or having a pre-existing condition? The awareness of any serious diagnosis may have traumatic psychological implications on a 16 year old. Should the government fund her to begin preventive care (such as a mastectomy) at that age?

 Similarly, is a carrier of a genetic disease state such as Tay Sachs disease, considered ill even though carriers appear to have no medical symptoms or adversities? However, if two carriers marry, then 25% of their children will be born with this fatal condition. These medical considerations intersect directly with bioethical concerns with respect to eugenics or designer babies. For example, many ethicists believe it is moral to undergo pre-implantation genetic diagnosis (PGD) to eliminate those in vitro-fertilized eggs that carry two genes for Tay Sachs disease. How, would they deem it ethical to destroy those in vitro-fertilized eggs that only carry one gene for Tay Sachs and who will not be born with this condition? At the other extreme, can parents who are hearing impaired use PGD to select a child who is also hearing impaired, to better fit into their world? These are just some difficult questions that ethicists are currently debating and highlight the need to refine bioethical principles to address these issues.

 **Conclusions**

There are many diverse theories regarding medical ethics that have been applied to bioethical dilemmas. In this book, we propose that resolving these dilemmas requires a multidisciplinary approach that ideally should integrate philosophy-based theories with the understanding of the underlying science. In addition, any attempt to resolve bioethical issues should consider an historical review to assess whether there are important lessons that can be learned from previous bioethical dilemmas that we, as a society, have already faced.

**CASE STUDY-**

**In early 2002, a lesbian couple who both had a congenital hearing impairment wanted to have a child with the same genetic impairment. They obtained sperm for artificial insemination from a donor with a heritable form of deafness to increase their chances and so far have two children with hearing impairment. In contrast, another hearing impaired couple utilized PGD to have a child who exhibited normal hearing function. Did just one of these couples engage in ethical behavior?**

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