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 good, evil, ethical behavior and unethical behavior is one major force motivating humanity to establish a set of beliefs and values that will result in the most good for the greatest number of people.

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. 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. Other philosophers question whether emotions or culture should be considered in developing ethical principles. 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 be included to guide moral decisions. Interestingly, brain-scanning technology support the idea that both rational and instinct influence moral choices (Shenhav and Greene, 2010). Green views the moral brain 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. Emotional responses, which are influenced by humans’ biological makeup and social experiences, are like the presets: fast and efficient, but also mindless and inflexible. Rationality is like

manual mode: adaptable to all kinds of unique scenarios, but time-consuming and cumbersome.

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 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 in order 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 all actions are vital in any decision-making process

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 produced 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 to resolve issues of bioethics or medical ethics. However, common steps in analyzing bioethical dilemmas include:

1. *Identifying and recognizing the specific ethical issues for any case.*
2. *Identifying the key facts*, *important definitions, and what remains to be discovered in a particular case*.
3. *Identifying the stakeholders.* Are the stakeholders in a case the research scientists, patients, or commercial companies supporting research that will generate profits?
4. *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?
5. *Evaluating how a course of action will impact the specific issues and their impact on other related social or biomedical issues.*
6. *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 resolved 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 as a 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. A historical look at 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.

Hierarchy of Bioethical Guidelines

One major challenge in presenting bioethical guidelines is how to establish a hierarchy of which guideline should take precedence in a situation that involves

multiple conflicts. 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? Often introducing new biotechnologies into a clinical situation is extremely expensive which limits who can partake in these new procedures. 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).

Some bioethicists argue that the principle of utility must be applied to each case that elicits bioethical challenges. The principle of utility states that we should produce the most favorable balance of benefit over harm for all concerned. Various states in the USA allow parents not to vaccinate their children for religious reasons. While this law acknowledges religious freedom, it also can cause severe consequences, such as the many cases of infectious disease outbreaks that could have been prevented via vaccines.

Another example is capital punishment. Currently physicians are not allowed to administer lethal drugs for capital punishment because it violates the guideline of beneficence. So non-medical individuals are now trained to administer the drugs and physicians are allowed to observe treatment. However, there are several reports claiming that administering lethal drugs to prisoners convicted to death is not a simple procedure and unanticipated adverse events occur during executions (Kas, Yim et al. 2015). There are dozens of reports of inhumane executions. Most states employ a three-drug protocol comprising of sodium thiopental, pancuronium bromide, and potassium chloride. In 2016, several companies that produce these drugs are refusing to manufacture them for lethal injections because of their ethical views concerning capital punishment. The ethical unresolved question is whether convicted criminals have the same death rights as everyone else?

What is a disease?

Any discussion of bioethics in the 21st century has to focus on defining what a human disease means in scientific, legal, 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 neither precise nor scientific because it is unclear whether health, illness, and disease are purely biological in nature. In fact, biological approaches to chronic illness often do not produce the anticipated effects. 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 some scholars to propose a 'reverse view' concept of disease, outlining that the development of disease 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. Another example relates to the term "disease free survival" in cancer patient that implies that these individuals do not present any outward symptoms of the cancer even though they may harbor cancer cells within their bodies.

Finally, one needs to distinguish between a drug and a cosmetic. The Federal Food, Drug, and Cosmetic Act defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance". The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man. Some products meet the definitions of both cosmetics and drugs. A shampoo, for example, can be defined as a cosmetic because its intended use is to cleanse the hair as well as a drug because of its antidandruff properties.

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 diseased 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 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, and without a code, there is 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. According to the Journal of American Medicine (JAMA), one-third of all adults in the United States are obese. Obesity occurs when Body Mass Index (BMI) reaches 30 percent, and morbid obesity is defined by a BMI of greater than 40 percent. An obesity diagnosis alone does not qualify an individual for disability benefits. Yet, there are circumstances under which an obese person may meet Social Security disability medical eligibility requirements. These include cases where a person's BMI is so high that they are unable to move, walk, or complete everyday tasks like preparing food, cleaning their home, or dressing or bathing. This policy change allowed millions of overweight Americans to make medical claims for treatments such as bariatric (stomach) surgery and prescription diet regimens.

Autism is a disease that has been difficult to categorize. Autism was first identified in 1943 by psychologist Leo Kanner who reported aberrant behaviors in children such as "insistence on sameness," and "autistic aloneness." Since then, these criteria have been delineated and reformulated multiple times to yield the current characterization of autism spectrum disorders (ASD) as identified by the DSM-V, the standard manual used in identifying and diagnosing mental disorders. Today, autism spectrum affects about one out of every sixty-eight children in the United States. The incidence of autism seems to be on the rise, yet researchers are still unable to determine the etiology of this disorder or how genetics or environment contributes to disease onset. Is the observed growth of this developmental disorder artificially induced by redefining the disease or by employing better diagnostic tools and earlier screening? Could there be environmental factors that are interfering with normal neurodevelopment? The re-definition of autism via symptoms rather than pathological signs has generated many questions and has required researchers to re-examine genetic and environmental factors that may contribute to the pathology as well as the ways medicine screens for this multifaceted disease.

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. 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?

Today, we are entering an era where DNA analysis, precision medicine (see Chapter 11) and biomarker analysis are used to predict the onset of future diseases, even before any symptoms appear in the targeted individual. The response of the public towards view these types of analyses remain to be determined, especially with regards to early treatment options, sustaining pregnancies where DNA mutations are detected in the fetus and whether early intervention should be covered by medical insurance.

Another issue is 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 as a result of their disabilities.

Ethical and definitional quandaries regarding genetic testing 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 as having a pre-existing condition that should be treated with a mastectomy? The awareness of any serious diagnosis may have traumatic psychological implications on a 16-year-old. At what age should the government to begin fund her preventive care?

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? Statistically, 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 ethical 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 of the difficult questions that ethicists are currently debating which highlight the need to refine bioethical principles to address these issues.

CASE STUDY-

A married couple is expecting their first child. They undergo fetal DNA testing only to be told that their female fetus is carrying a BRAC1 gene. Statistically, this means that this child will have an 80% chance of developing breast cancer within 70 years. Aside from the issue of autonomy, it is ethical for the parents to terminate the pregnancy?

Financial repercussions of unethical behavior

It is important to consider some of the tremendous financial consequences of unethical practices. The vaccination scandal, is one example where millions of dollars were lost because of a Lancet report in 1998, authored by Dr. Andrew Wakefield, a British surgeon and medical researcher who allegedly found a connection between vaccines and the onset of autism. It took over 10 years until the report was deemed to be fraudulent and retracted by the journal Lancet. Yet the financial damage was huge. The reviewers of Lancet failed to recognize the paper's extreme scientific manipulations, a lack of good statistical analysis, (a small group of 12 children as test subjects), the absence of a control group, and the reliance on people's memories for vaccination records.

From 2003 to 2010, over ten large studies were conducted by the CDC, by other government agencies and medical institutions to re-establish the safety of vaccinations and to try to alleviate the public fears that vaccinations are linked to autism. The costs for these studies ran in the millions of dollars, and highlight the financial repercussions of medical and scientific fraud. In one study, researchers examined 291 articles originating from the United States and published between 1992 and 2012 that were retracted for research misconduct. The total cost for these research studies ran over $58 million including $19 million that were NIH-funded.

In addition, hundreds of thousands of patients have been placed at risk of improper medical care due to enrollment in fraudulent studies or the administration of treatment based on fraudulent studies. The medical costs and health risks these patients encountered are huge. Decreasing vaccination rates are often associated with outbreaks of preventable infections, such as a recent measles outbreak in Wales that resulted in more than 1200 cases and cost an estimated $800,000 US) (Stern, Casadevall et al. 2014). In summary, robust science needs robust processes of review, transparencies, and enforcements to maintain ethical practices in publishing data.

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 knowledge 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 our society has already faced.

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