Evidence-Based Medicine and Bioethics: Implications for Health Care Organizations, Clinicians, and Patients

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ABSTRACT

Since its beginning in the 1990s, enthusiasm for evidence-based medicine (EBM) has flourished. As its methodology becomes more sophisticated and its breadth expands, EBM increasingly is referred to in patient care, insurance coverage decisions, technology assessments, medical education, and health care policymaking. Despite this growth, the intersection of EBM and bioethics often is not explored.

This article discusses the deontologic and utilitarian aspects of EBM and assesses EBM according to 4 bioethical principles: Respect for autonomy, beneficence, nonmaleficence, and justice. Strong ethical arguments support EBM as the best approach to patient care. However, practitioners and health care organizations must be aware that each principle involves complex issues that challenge EBM’s ethical values.

INTRODUCTION

In an August 2017 monthly physician update from the Southern California Permanente Medical Group, Nicole Lorey, MA, Chief Communications Officer, described 6 pillars of Permanente Medicine: Patient centered, physician led, evidence based, team delivered, culturally responsive, and technology enabled. She went on to state that Permanente Medicine is ethical care. Without describing the ethics associated with all these pillars, I will discuss the ethics of evidence-based patient care from a treatment perspective (although many of the concepts presented likely apply to prevention, diagnosis, and prognosis as well). Assessing the ethics of evidence-based medicine (EBM) is important because professional societies, health care organizations, and insurance companies are encouraging clinicians to practice EBM with the underlying assumption being that it is an ethical approach to patient care. I will describe the ethical underpinnings and challenges surrounding an evidence-based approach to patient care by way of its 4 principles (respect for autonomy, beneficence, nonmaleficence, and justice).

Utilitarian and Deontological Evidence-Based Medicine Approaches

According to leading early proponents, EBM “is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected ... in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care.”

Thus, as originally formulated, EBM involved both quantitative and qualitative aspects.

A number of EBM approaches to treatments may be adopted. When using the standard approach, a clinical question leads to a systematic review. A literature search is performed using terms that cast a broad net across the medical literature. The retrieved articles are then reviewed against a set of inclusion and exclusion criteria for the clinical question and relevant articles are selected. These articles are assessed and the results are combined either qualitatively or quantitatively (e.g., in a meta-analysis). The conclusions of this analysis can then be translated into clinical practice guidelines on the basis of factors such as the weight and quality of evidence, patient values and preferences, and cost. This translation from evidence to guideline publication typically is accomplished with a multidisciplinary team. This process often necessitates substantial time and expense; consequently, organizations may use other methods when developing guidelines, such as reviewing previously published systematic reviews or adapting guidelines produced by other organizations.

Ethics approaches described in the West include utilitarian, deontologic, virtue, ethics of care, feminist, casuist, and liberation. The ethics underlying EBM involve both utilitarian and deontologic aspects. Let’s start with utilitarianism, which is a branch of consequentialism. In consequentialism, the right action is the one that maximizes good consequences and minimizes bad consequences.
question being asked. Treatment articles compare the results of a specific treatment (usually a new treatment) with either another treatment’s results (usually an established treatment) or placebo. Researchers are looking to determine which treatment maximizes good clinical outcomes in the research population without producing undue harm. Provided that similar articles have reported similar results as determined by our systematic review and provided there are no significant barriers to implementation, EBM would recommend we use the treatment that maximizes clinical outcomes for the most patients who have a specific condition. On the basis of these descriptions of utilitarianism and EBM goals, both appear to have similar approaches.

Utilitarianism has many critics because a strict utilitarian approach to patient care dictates that the end justifies the means, and some utilitarians are not particularly concerned about how we get to our end. For example, a utilitarian might not hesitate to take 1 kidney from a patient with 2 normal kidneys and give that kidney to a patient who is on dialysis because the greatest good is being done for the greatest number of people. The assumption is that the donor can live a healthy life with 1 kidney, and the recipient should now experience a better quality of life. A utilitarian might make this choice over a donor’s protests and without informed consent. Although this is an extreme example, it illustrates a common criticism of utilitarianism.

To counter this overreaching definition of utilitarianism, an ethical approach that takes into account patient rights and clinician or researcher duties and obligations is needed. This is the territory of the deontologist (from the Greek deon, meaning duty). In this example, the deontologist would not take the donor’s kidney without consent if clinicians had to respect patient autonomy or if a patient right stated that no surgical procedure would be allowed without consent and after disclosure of a procedure’s risks, benefits, and alternatives. In deontology, a person should not be used only as a means to reach another person’s goals but should be treated as an end in themselves. From a medical research perspective, deontology has been applied to human experimentation. Researchers are obligated to account for research subjects’ rights to carry out their studies, and subjects should provide voluntary informed consent before study enrollment. This approach respects autonomy and validates dignity. Subjects are not just a means to satisfy a researcher’s goals. These rights and obligations also protect subjects from unnecessary harm while maximizing potential benefit. Although this deontologic check on utilitarianism is important, it was put in place only relatively recently for human experimentation purposes.

A deontologist might feel obligated to take a certain action even if s/he knows that by doing so, a worse outcome may result. For example, in classical deontology, certain duties apply regardless of consequences such as keeping promises, telling the truth, and not killing innocent people. These absolute duties, however, may be problematic if they conflict with other duties such as beneficence or nonmaleficence. In 1 example, the psychiatrist treating James Holmes, the gunman in the 2012 Colorado movie theater mass shooting, was sued by the relatives of 1 of the victims. The plaintiffs claimed that the psychiatrist should have broken patient confidentiality and prioritized nonmaleficence by acting more assertively when she became concerned that her patient might be a danger to others.

Evidence-Based Medicine Ethics

EBM ethics incorporate aspects of both deontology and utilitarianism. For example, our population studies approach shares many aspects with utilitarian ethics, and our approach to medical research incorporates many deontology aspects. For several decades, a popular approach to understanding Western bioethics has involved the 4 principles. These principles—respect for autonomy, beneficence, nonmaleficence, and justice—initially were described by Beauchamp and Childress in 1979. The principles are deontologic and follow the prima facie (conditional) obligations initially described by WD Ross in 1930. Ross broke with classical deontologists to assert that there are no absolute duties, only conditional duties. When a conflict of duties arises, the duty that ultimately is chosen is based on the circumstances of that particular case.

The ethical concepts of beneficence and nonmaleficence warrant definition and discussion. Beneficence entails promoting the well-being of others; nonmaleficence is an intention to avoid harming or injuring others. Although head-to-head comparisons of EBM and other approaches to patient care are not readily available, we can argue that it is our moral duty to follow an EBM approach because it allows practitioners to determine the true benefits and harms of a particular intervention. The EBM process described earlier led us to reach conclusions and to provide recommendations on the basis of the medical literature. We are less confident about true benefits and harms if we let tradition or expert opinion guide our practice. Using an EBM approach, we should be able to distinguish the range of benefits and harms among possible treatment options. And provided there is little difference between efficacy and effectiveness for a particular intervention, patient, or population, we should be able to quantify both benefits and harms (eg, number needed to treat, number needed to harm, etc). Among all patient care approaches, EBM should foster confidence that we are providing beneficent and nonmaleficient care.

However, issues in the medical research and publication process can affect certainty regarding beneficence and nonmaleficence. For example, we know from the pediatric literature that about one-half of pediatric trials are not completed or do not get published, and industry-sponsored pediatric trials are twice as likely to go unpublished. We also know that industry may suppress publication of research results if the data have adverse marketing implications. Besides publication bias, ethical issues arise regarding published yet underpowered studies. These studies may contain type II errors; there may be a difference in treatments studied, but researchers have not identified the difference and may conclude that treatments are equivalent (a larger trial might demonstrate a new treatment as inferior to an established treatment). Selection, reporting, and attrition bias also may exist. Although EBM possesses tools that allow us to identify and to adjust for biases (eg, funnel plot, power analysis, Cochrane risk of bias tool), to some extent EBM investigators
are at the mercy of the research establishment and the way in which it conducts and publishes its research.

Other issues may affect certainty regarding beneficence and nonmaleficence. There may be large differences between efficacy and effectiveness. Data frequently originate from optimized, resource-intensive care processes that may not translate well into the real world. Also, patients can be harmed when practitioners follow EBM too rigidly and adhere to evidence-based clinical practice guidelines without accounting for unique patient situations. These biases and other issues have ethical implications because they make predictions of beneficence and nonmaleficence on the basis of EBM less certain. Guideline developers who take these biases and other issues into account likely will produce more ethical guidelines than those who do not. Searching and adjusting for these biases may be time- and resource-consuming, but the effort and expense likely will provide value in the end.

Patient Autonomy and Bias

Autonomy entails respecting the right of another individual to determine that person’s own course. This definition fits nicely with the EBM injunction to account for patient preferences. However, EBM has been criticized for overemphasizing the calculated science of medical research and deemphasizing patient values and preferences. Although values and preferences typically are not accounted for in individual research articles or during systematic reviews, they may be considered when clinical practice guidelines are developed. A recent structured approach to guideline development (GRADE: Grading of Recommendations, Assessment, Development and Evaluation) lists 4 factors, each to be assigned a value when determining strength of a recommendation: Patient values and preferences, balance between desirable and undesirable effects, quality of evidence, and costs. Patient values and preferences apply at the population level; ideally, patients or patient advocacy groups have input into scoring this factor. If population values and preferences are uncertain or vary substantially, this factor gets a low score, and the overall strength of a recommendation may be reduced. Although consideration of patient values and preferences is laudable, we see a number of challenges. If guideline developers do not use GRADE or a similar approach, values and preferences will not be considered. If the applicable population is variable, as it will be in many urban environments, or if the geographic area is large (such as the case for many health care organizations), the population likely will be diverse. Determining population values and preferences under these circumstances can be challenging. Several studies have demonstrated that values and preferences among patients in similar situations are variable. Also, the processes and tools for accounting of values and preferences are not standardized.

Another challenge regarding autonomy is that the ethical perspective of a patient may differ from the ethical perspective of a health care organization. We might say that a patient’s goal during his/her clinical encounter is consequential but not from a utilitarian perspective. A patient is interested in getting well and usually is less concerned, or not concerned, about how diagnosis and treatment affects the larger population (although s/he may have some concerns about effects on family, friends, or coworkers). This patient likely will value personal wellness and prefer that the consequences of treatment will quickly lead to a better state of health. This self-interest appears to have elements of egoism in which the best ethical actions are those that maximize a person’s own welfare. Although egoism frequently is regarded in a negative light, it is common during clinical encounters. A patient’s self-interest goal may not align with the population-interest goal of a health care organization, and this can pose a challenge when costs are involved. Some patients may want treatment that provides only a small incremental benefit at a large cost, whereas a health care organization may take the utilitarian approach, contending that those resources are better used in treating other patients for greater benefit.

From a clinician perspective, patient values and preferences typically are addressed at the individual patient level. This can lead to major ethical dilemmas for practitioners who may find themselves caught between values and preferences of both the patient and health care organization as reflected in evidence-based guideline recommendations. Although shared decision making that involves a discussion of benefits, harms, alternatives, and costs likely is the best approach in these situations, discussion outcomes may conflict with guideline recommendations depending upon how much flexibility the guideline allows for the shared decision-making process. Some studies have demonstrated that clinician values and preferences frequently are at odds with patients’ values and preferences. It is unclear how much of this discordance reflects a clinician’s values and how much it reflects a clinician’s role as the organization’s representative. This discordance can be compounded if a health care system is monitoring practitioner adherence to guidelines and patient satisfaction with individual practitioners. Some regulatory agencies do not penalize a practitioner or institution if a patient’s preferences do not meet regulatory requirements.

It may be difficult for EBM practitioners to fully acknowledge patient autonomy for all of these reasons. Patient values and preferences, if taken into account at all, are at the population level when guidelines are produced, and they may not represent the values and preferences of individual patients. Furthermore, the ethical approach of the health care organization, as reflected in its guidelines, more closely resembles utilitarianism, whereas the ethical approach during patient encounters more closely resembles egoism. The goals of these approaches may clash, the clinician may be caught in the middle, and EBM may not be particularly ethical when it comes to respecting autonomy.
Justice in the setting of EBM warrants discussion as well. According to Beauchamp and Childress, “Justice [is] fair, equitable, and appropriate treatment in light is what is due or owed to persons... Injustice involves a wrongful act or omission that denies people resources or protections to which they have a right.” Provided that inclusion or exclusion study criteria are not biased, EBM should promote justice to individuals and groups because it provides scientific guidance on the best treatments for patients with specific conditions regardless of characteristics such as sex, race, or socioeconomic status. Health care disparities, which are well documented, are closely related to access to services, economic inequality, language barriers, and biased health care systems.  

Injustice can result from study design and publication bias and also from funding bias. An example is funding for cystic fibrosis (CF) and sickle cell disease (SCD) research. The severity of these 2 illnesses is similar. Despite the fact that CF prevalence is one-third that of SCD, research funding for CF is an order of magnitude higher than funding for SCD. This increased funding probably has resulted in twice as many CF publications as SCD publications and more FDA-approved medications for CF than SCD. Because EBM reflects published research, more evidence will emerge and may lead to higher-level evidence-based recommendations for CF than for SCD. It is no secret that most people with CF are white and that SCD almost exclusively occurs in blacks. A bioethicist looking at this data probably would say that an injustice is affecting a marginalized society on the basis of race. This is in keeping with the perspective of liberation ethics that those at the margins of society are kept at the margins by systematic biases against them promulgated by the “majority society.” In this case, the majority society is composed of funding institutions and a research community that drive medical research and publications. Although EBM is the recipient and not the cause of these biases, EBM still reflects bias through the reporting of evidence. As with beneficence, nonmaleficence, and respect for autonomy, justice issues may render EBM less ethical when these issues reflect unjust research and publication processes.

DISCUSSION

EBM ethics have both utilitarian and deontologic aspects. The medical literature recommends treatments that produce the greatest good for the greatest number; researchers and clinicians should perform certain duties for patients and to respect patient rights. Among the various approaches to patient care, an evidence-based approach should be most ethical because those who employ it seek to quantify patient benefits and harms. Clinicians and patients with knowledge of these benefits and harms should be able to make more sound treatment decisions. EBM-related issues may make this approach less ethical, however.

No head-to-head studies have compared EBM with other approaches to patient care. In theory, EBM should be most ethical because it introduces scientific rigor. Practitioners should be able to more accurately predict the benefits and harms of specific treatments and provide beneficent and nonmaleficient care to their patients. However, ethical problems arise when biases influence the EBM process. Such issues render predictions of benefits and harms less reliable and EBM potentially less ethical. Guideline developers who account for these biases and other issues more likely will produce a more accurate guideline and better serve patients and clinicians.

EBM originally was designed to account for patient preferences. However, it is difficult to regard individual patient values and preferences when the accounting of values and preferences during the guideline development process takes place at the population level. Also, health care organization and patient goals may differ. The health care organization usually takes a more utilitarian approach and values the health of the population. The patient takes a more egoist approach and values his/her own health more so than population health. Ethical dilemmas arise for practitioners when patient values and preferences conflict with organization-sponsored, evidence-based recommendations. A shared decision-making process likely is needed to reach the best solution.

Because of its rigorous methodology, EBM should support justice and help to decrease health care disparities. However, EBM reflects decisions about funding, study design, and publication and consequently reflects any injustices inherent in these decisions. As a result, health care organization leaders must realize that EBM may not be as accurate as originally constructed. Some EBM issues can be addressed during the guideline development process, but many issues cannot be addressed because EBM is at the receiving end of the medical research and publication process. To more effectively ensure beneficence and nonmalefice, organizations that create guidelines should strive to address as many biases as possible. Organizations that develop guidelines must carefully review all content to reduce potential bias and fully deploy their guidelines so clinicians can discuss the evidence during meaningful patient encounters.

CONCLUSION

Clinicians and patients may arrive at shared decisions that conflict with organizational guidelines. Organizations should accept the outcomes of these discussions to support patient autonomy. Clinicians and patients should be allowed to opt-out of a guideline recommendation (with reasons cited), and organizations should not force clinicians into ethical dilemmas in which they are caught between organizational expectations and patient values and preferences. This degree of latitude will go far toward supporting collaborative patient-centered care and respecting patient values, preferences, and shared decision making.

Health care organizations should produce guidelines for treatment of conditions unique to marginalized populations. Guideline topics often are chosen on the basis of disease prevalence or cost—a utilitarian approach. Utilitarianism can harm the minority to the benefit of the majority, but harm may be reduced by addressing minority health care needs and potentially decreasing disparities.

Clinicians should be familiar with the evidence behind treatments and feel empowered to deviate from evidence-based recommendations for a good cause. They should encourage...
patients to discuss their values and preferences and make shared decisions. Patients should be open to the evidence presented during clinical encounters yet feel empowered to discuss their own values and preferences and make decisions that may contradict guideline recommendations.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgment

Brenda Moss Feinberg, ELS, provided editorial assistance.

How to Cite this Article


References


Keywords: bioethics, EBM, evidence-based medicine, GRADE, guidelines, Western medicine, autonomy, beneficence, nonmaleficence, and justice