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Values-Based Medicine (VsBM) and Evidence-Based Medicine (EBM)

Ahmed Ammar

Abstract

Medical care is a dynamic process to implement and use the most recent technologies, skills, and knowledge to either maintain the good health of people or to treat sick patients. Patients have the right to receive the best possible available treatment. During the course of treatment, the patient's dignity and rights should be respected and never be compromised. A patient's right to be properly treated is one of the fundamental human rights. The healthcare system is responsible for providing efficient and sufficient healthcare facilities and training and continuously educating able medical and paramedical teams. Evidence-based medicine has been popularized in the last 40–50 years in order to raise the standard of medical practice. Medical ethics and values have been associated with medical practice for thousands of years since patients felt the need for treatment. There is no conflict between evidence-based medicine and values-based medicine, as the medical practice should be always preformed within a frame of ethics and respect of patient's values. Observing the principles of values-based medicine became very relevant as multicultural societies are dominant in some countries and hospitals in different corners of the world.

Keywords: values-based medicine, bioethics, patient's rights, education, dignity, history of medical ethics

1. Introduction

Conventional clinical relationships are centered on a triad, consisting of the physician, the patient, and his/her family. Nowadays, individuals in need or seeking medical care, as well as their intimate circle, interact with a great variety of stakeholders and clustered interests. Three important factors contribute to this more complex situation.

The progress of life sciences and technological innovations as well as the development of the health system and the medical-industrial complex create new medical situations and redefine the role of both family members and health professionals.

The potential of modern healthcare, including resuscitation and life-sustaining technologies, their impact on the quality of life, as well as problems of costs and resource allocation in the context of market economies, also redefine the role of family members. This opens a myriad of ethical questions, from coping with frail,

sick, or disabled relatives, over socialization and commercialization of traditional household tasks, to substitute decision-making for minors and patients with diminished autonomy, as well as dealing with end-of-life situations.

The nature of neurosurgical problems forces neurosurgeons to face their patients' families in different emotional situations, frustrated to see good results, disappointed with the outcome, confused, denying, or angry. Neurosurgeons should learn the skill to absorb the first reaction of the patients' family and work with them as one team to help their loved one. The patient's family can play a very positive part in the caregiving team for the patient and may have a great and unreplaceable input for their patient care.

2. Definition and the concept of values-based medicine

Values-based medicine (VsBM) is the concept to ensure that the principles of medical ethics are strictly implemented and observed in every step of a patient's management.

Values-based medicine can be defined as “medical practice that aims at maximizing value, specifically desirable or positive value in every step of a patient's medical management”.

The concept of values-based medicine (VsBM) stresses on the fact that patient, patient care, and well-being are the center of care in modern medicine. The treating neurosurgeons, physicians, or healthcare givers should spare no effort to improve their skills, update their knowledge, and learn to use the latest technology in order to provide the best care for the patient. The treating team should have a vision and build up a strategy of management and follow-up of their patients. All these necessary steps should be performed within a frame of values and medical ethics. The treating teams should respect and observe the patient and value and respect the culture of the society. Evidence-based medicine should be considered an important component of values-based medicine [1]. The key elements of values-based medicine which, like evidence-based medicine, influence any clinical decisions may be taken for patients' management (Figure 1).

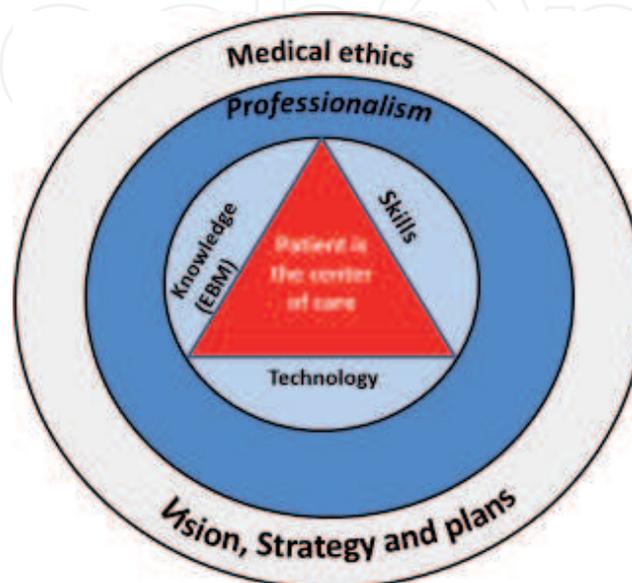


Figure 1.
The concept of values-based medicine (VsBM): patient is the center of care.

3. The principles of medical ethics

Based on the Hippocratic Oath, the main ethical principles were beneficence (do the best for patients) and non-maleficence (do no harm). These two principles were considered to be the fundamental principles of medical ethics for hundreds of years. The principles of medical ethics/bioethics were expanded to include autonomy (patient's right to accept or refuse the method of treatment) and justice. Justice in medicine considers the distribution of healthcare facilities and the access of all patients to these facilities. One of the positive characters of the last and this century is the respect and observation of human rights. Therefore the human rights were manifested clearly in the medical ethics, as the medical ethics expanded again to (a) autonomy, (b) beneficence, (c) non-maleficence, (d) justice, (e) dignity, and (f) truthfulness and honesty. **Figure 2** demonstrates these principles.

3.1 Patients' rights

The respect of patients' rights is one of the main foundations of the concept of values-based medicine. Patients should be considered as partners and share in the process of management. Patients should agree and consent to every step of treatment. Patients have the right to be fairly and properly treated; follow-up should be guaranteed. A patient's privacy, dignity, and confidentiality should be respected. Dignity encompasses a feeling of self-worth and equality. It is paramount that the patient be treated as a person with a disease, rather than a disease that a person has. The patient should also feel he is an equal partner in decision-making, and not just a bystander or subordinate. Patients should be educated and learn about their medical problems, treatment options, and the prognosis. Patients must know who the treating team is, their experiences and qualifications. Patients should have the right to complain in the cases of dissatisfaction about the treatment or lack of communication. Most of these rights are illustrated in **Figure 3**. These fundamental human rights are listed in the WHO recommendation [2] and the World Federation of Neurological Societies as good practice guideline [3].

3.2 The duties and task of the treating teams

The concept of values-based medicine draws the outlines of the duties and tasks of the treating team as illustrated in **Figure 4**. These duties include respecting the

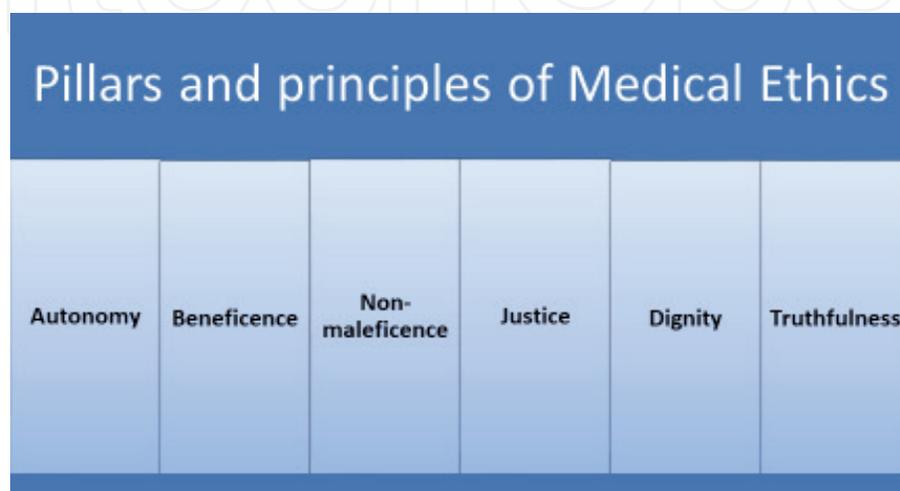


Figure 2.
The principles of medical ethics.

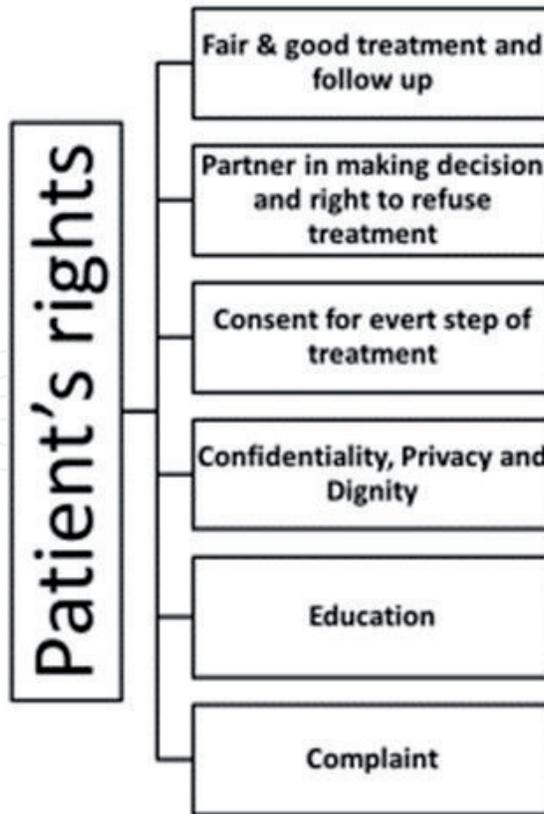


Figure 3.
The Patient's rights.

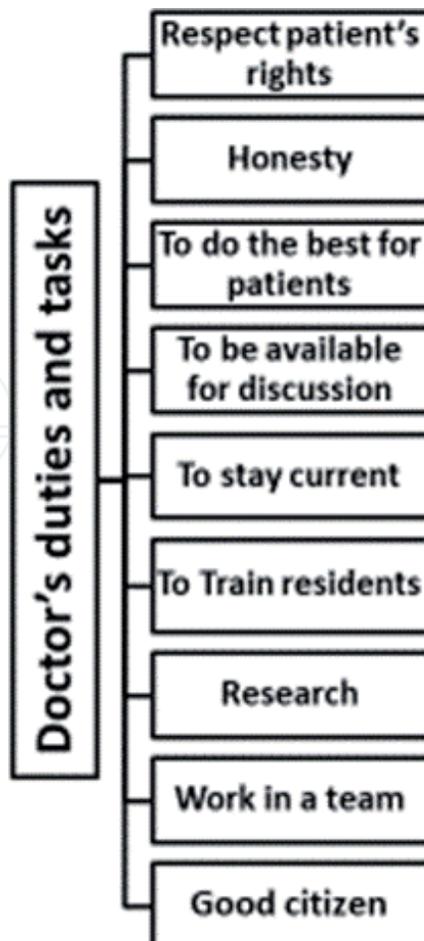


Figure 4.
The tasks and duties of a medical team.

patient and preserving their dignity. It is the duty of every doctor to improve skills and update the knowledge. Doctors should research answers to previously unanswered medical questions. Doctors should be good citizens and advocate for good health. They should maintain a high level of professionalism at all times.

4. Ethical relativism

Healthcare is considered as a universal human right. Culture, faith, socioeconomic factors, and the perception of the value of the education, work, and status of doctors in differing societies are some of the causes of the variance of healthcare in those societies. That variance cannot be deemed as right or wrong, which led to the study and introduction of ethical relativism. Ethical relativism is the view that there are no ethical standards that are absolutely true and must be applied to the societies, without variance. According to the Relativism Theory, a certain event, attitude, or practice may be considered right, if it is accepted as morally correct by the people of the involved society. The same event or attitude may be considered wrong by a society that does not accept it as morally correct.

Throughout the world, most neurosurgical training programs are designed to produce safe, effective neurosurgeons trained to find evidence for the treatment of different neurosurgical problems [4].

Neurosurgeons are obliged to establish ethical and professional relationships with their patients and to that end, should listen to and be guided by both the patient's medical complaint and their perception of the possible outcomes. It is the duty of neurosurgeons to explain to their patients all the steps of investigation, treatment, operation, and possible outcome.

The neurosurgeon can gain valuable knowledge of the patient's culture and beliefs while discussing the benefits and risks of a particular method of management during the course of obtaining informed consent. This knowledge and exchange of information assist in gaining the patient's respect and trust and compliance for both the agreed-upon treatment and its follow-up. Ethical informed consent requires that autonomy and beneficence are applied in equal measure. In applying beneficence, at the expense of autonomy, neurosurgeons may cause irreparable psychological damage [5–7]. Pressure or influence for a particular course of treatment can never be considered ethical, because, although it may be applying the principle of beneficence, it is at the expense of autonomy.

5. Evidence-based medicine (EBM) and values-based medicine (VsBM)/ EBM and VsBM

5.1 What is medical evidence?

An "evidence" is considered as evidence according to data of a particular cohort study under particular condition of some patient group somewhere. Several scholars and ethicists have raised concern about using the stereotype of evidence to promote a chosen type of therapy or surgery [8]. This attitude may cause bias in selecting evidence to justify certain methods of treatment.

Ross defined the clinical evidence as "In essence, evidence—narrowly defined or not—is a provisional departure point in the consideration of whether or not a particular course of action is to be taken in any clinical context." [9] This definition directly links the evidence to its application but not to the strength, validity, and reliability of the source of that evidence.

5.2 Evidence-based medicine: definitions and impact on medical practice

The introduction of evidence-based medicine 40–50 years ago had a great impact on medical practice almost everywhere. That concept became very popular in a very short time. The main reason being that it offers a strong foundation for the justification of decision-making in the course of management of clinical cases. The evidence-based medicine was defined by El Kayaly et al. as “Evidence-based clinical medicine can be seen as the conscious incorporation of the best evidence that is currently available into daily clinical practice covering prevention, diagnostics, clinical assessments, treatments and patient-centered care” [10]. The implementation of the concept of EBM is significantly helpful and challenging for many practitioners for several reasons such as:

- a. EBM aims to manage uncertainty regarding the short- and long-term outcome of management of certain cases. However, this aim cannot be always achieved.
- b. From the physicians’ perspective, the conscious belief of the treating team that the best evidence and recommended method of a case management is followed has a definitely positive impact on the treating team and increases their confidence about the line of treatment they decided to choose.
- c. In the cases when good and suitable evidence are not found or not agreed about, the integration of the principles of values-based medicine is a must.
- d. From the patients’ perspective, knowing that the course of management offered to them is supported by good evidence helps the patient and his family to accept that method of treatment. The patient’s perception of receiving treatment according to EBM has good psychological impact.
- e. In the cases of medical litigation or argument, the documents of the best evidence have an important value to balance the argument. EBM documents should have an important value in a court of law.
- f. EBM has also important educational values as it challenges all the practitioners to continuously update their knowledge in the course of their striving to find the best evidence. It definitely promotes the practitioners’ professional development. EBM seeks to inculcate lifelong learning process.

6. Clinical application of EBM: considerations

In daily clinical practice, the application and implementation of EBM simply means that choosing a treatment for a patient is based on the strongest available evidence. However, the concept of EBM does not consider as much, but should consider patient’s values and beliefs or other factors such as experiences of the treating team and facilities available at that hospital. Sackett et al. defined EBM as “Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values” [11]. In that definition “Patient values” is not clearly explained in that definition which may refer to what does the patient want? In fact, the implementation of EBM does not generally seek patients sharing in decision-making. The science, practice, and application of EBM do not consider that patient’s values, faith, and culture are factors for grading or leveling evidence (hierarchy of evidence). Several studies showed the importance of the patient being a partner in decision-making [12, 13].

7. How evidence is ethically evidence?

Evidence-based medicine has been popularized in the last 30 years and to a certain extent has been considered a good measure of medical practice. However, the use of EBM shows these limitations:

- I. Patient preferences and values were not always considered during the decision-making process [7].
- II. Limitations in incorporating health-related quality of life (HRQoL) [14] .
- III. EBM is based on finding and following the highest-quality evidence. However, in the absence of randomized clinical trials, the veracity of the evidence comes into question.

8. Collecting evidence

Ethically there are a few serious questions regarding presumed evidence collection. Those queries are legitimate as most of the evidence is obtained from the analysis of large data (meta-analysis) which has subsequently inherited all the problems of analyzing the large data of multiple sources. This problem has been discussed by several authors including Dagi [15]. He mentioned “The ethical question is what to do about the data once it has been collected and analyzed. It is ethically important to separate the results of statistical analysis from, for example, [1] statistically significant but clinically irrelevant outcomes, [2] judgments about how data about the set should be applied to specific individuals within the set, [3] the protection of the prerogatives of individual patients in the face of population-based protocols, and [4] the protection of the surgeon’s prerogatives in personalizing the treatment of individual patients. The question of what should be done with probabilities and statistics is not statistical in the least: it is entirely a value judgment.” Both scientifically and ethically, there is a clear line between what is considered fact and what should be or ought to be. The philosophical debate about is/ought (fact/value) has continued for hundreds of years and remains unsettled. Hume produced what is called Hume’s law “From causes which appear similar we expect similar effects. This is the sum of all our experimental conclusions.” He recognized as well the “is-ought” controversy. The idea of linking what ought to be to what is, is seriously ethically and clinically challenged.

Randomized controlled studies are the main factors that were used to level validity and strength of evidence. The value of evidence from randomized controlled studies is considered the strongest or best evidence and top leveled and graded as “Grade I Evidence.” Evidence obtained from nonrandomized studies is considered as “Grade II Evidence.” However, evidence based on valid experiences and thoughts and opinions of distinguished medical and surgical authorities are considered as “Grade III Evidence.”

Ethical concerns have been raised about double-blind randomized controlled studies. It has been debated that denying a group of patients (control group), the experimental treatment or method of management believed to be beneficial, is ethically challenged. There is also an ethical issue concerning the validity of evidence which is a result of double-blind randomized controlled studies which were carried out in certain circumstances, homogenous or not subjects, variable controls, and particular role to be used as the base for making decision for treating patients in different circumstances. Therefore, the integration of the best research evidence with clinical expertise and patient values should be carefully and cautiously considered.

There is a very important and distinct difference between the methods and approaches of clinical randomized controlled studies and the methods and approaches to established treatment. In the cases of clinical research, the physician (researcher in that case) and the patient are not standing on the same platform and may not have the same motivation and goals of the treatment. Therefore ideal clinical equipoise may not be achieved in such cases. Clinical equipoise should be carefully observed in any clinical research. The patient-physician relationship is a complex relationship regardless of the circumstances or the status of the patient. The patient has rights which should be and must be respected fully. The treating physician or surgeon should be a partner who has the main task to provide the best available treatment to the patient and share the very same goals with patient to cure the medical illness.

Respecting and observing patient values and quality of life are core to the implementation of VsBM. These principles and values somehow are overlooked by evidence-based medicine [12, 13].

The obtained and presented clinical evidence should not be out of the ethics frame (values-based medicine). The evidence should be valid and applicable in that particular condition, scientifically proven and adherent to the ethical principles and rules. VsBM and EBM should be integrated in daily medical practice and medical research. Ross [9] wrote “attention to evidence, however conceived, is linked to commitment to care. Rather than being seen as distinct spheres, ethics and evidence become part of an integrated whole.”

9. Theories of ethics

The core of the concept of values-based medicine is to value the human being's dignity and respect patient's rights and lay a foundation for ethical and meaningful good medical practice. Values-based medicine is an expression of medical ethics, considering patient as the center of care. So the frequent question of the clinician is “what is the best management for that particular patient?” If the uncertainty is the answer, the question should be brought as “which method of management ought to be better for that particular patient?” The answer to this question should be based on both clinical evidence and ethical values. Medical ethics should guide decisions in the daily medical practice. There are several branches of ethics which are normative ethics, applied ethics, descriptive ethics, and metaethics.

9.1 Normative ethics

Normative ethics are ethical theories which highlight what is morally right or wrong in order to lead to proper decision. Normative ethics constitutes/includes/is explained by several ethical theories, including:

- a. **Deontological theory**—which suggests that means may justify the ends. Deontological theory considers the moral rights according to observing laws and authorities.
- b. **Consequentialist theory**—which suggests the ends justify the means. It is an outcome-based ethic that says the moral right depends on the positive results.
- c. **Virtue theory**—this theory's roots go back to Aristotle's which focused on the inherent person more than an analysis of the person's deeds. According to this theory, the characters of individuals or groups prevail.

- d. **Ethic of caring theory**—which considers the subjective values is the determining factor to identify what is right and what is wrong. This theory suggests that relationships should be a deciding factor in deciding what is right and wrong.
- e. **Ethical intuitionism theory**—which suggests that intuitions may be distorted by not accurate or complete information, prejudice, and bias.

9.2 Applied ethics

Applied ethics may be described as it mandates the professional code of ethics or ethical guidelines for a certain profession such as medical profession or counseling.

9.3 Descriptive ethics

Comparative ethics focus on the beliefs of individuals, what people believe. Descriptive ethics is concerned with what is believed, not what should be believed.

9.4 Meta ethics

This type of ethics is mainly concerned with the ethics itself. Metaethics studies the nature of values.

10. VsBM: professionalism and professional ethics (separatists)

Medical professionalism in this context encompasses all qualities obtained and expressed to conduct or perform tasks and medical duties as described by the governing organization and hospital and as expected by the society.

11. Professional ethics

Professional ethics is the use of knowledge and skills to providing patient care governed by the ethical code of the workplace [16]. It is akin to moving from abstract values to daily behavior of individuals in their workplaces or societies.

Professional ethics (as it is one of the elements of values-based medicine) should observe values and standards of medical professionals and their medical societies, along with the expected behavior of the organizations and hospitals [17]. Medical professionals have to continuously gain and update their knowledge and skills in order to improve their career and consequently the patient's care. Medical researchers strive to find facts either in deductive or inductive ways. That effort should be governed by values and ethics of the patients and patients' culture and beliefs, not purely the eagerness to obtain knowledge or achieve professional goals [9, 18, 19].

12. Code of ethics

The code of medical ethics is general ethical guidelines adopted by medical societies, organizations, and hospitals. The code is mandatory for all medical and paramedical professionals in that organization to strictly observe. The code of ethics is not only for the benefit of patients but also for benefit for the medical and paramedical professionals.

13. Decision-making

Professional decision-making cannot be overemphasized in medicine in general and neurosurgery in particular. The medical professional should be able to balance the principles of values-based medicine within the roles of the governing organization and hospital. This balance is very important to avoid conflicts of patient's values or hospital policies.

The most critical step in patient management is the decision made by the treating team. The correct decision for a particular patient at the right time is the most determinative factor for the outcome of management. Medical decision-making depends on empirical knowledge and rational and analytical thinking. Evidence-based medicine depends on knowledge and accumulated information over rational thinking and individual experiences and to a certain extent ignores the patient's own values. In brief, there are in general two ways of logical thinking in order to make medical decisions, deductive and inductive methods. However, the rapid development of science, discoveries, medical technology, understanding the roots of pathophysiological disorders, and introduction of new treatments should allow for a less tightly constructed and rigid clinical decision. With uncertainty, the increased probability of causing risk, unsure outcome, and treatment of specific problems in a field like neurosurgery, the patient's autonomy and values should be paramount. The concept of values-based medicine which focuses on patient's best care allows more flexibility to adapt any scientific method which may help the patient. Patient and patient values should be part of any management equation.

The patient's family rights should be observed. The engagement of the patient and patient's family in making decisions created what is called "Patient-patient's family-doctor complex relationship." Such relationship is needed not only for the patient's comfort and well-being but also for the treating team to prevent any misconduct and future unnecessary troubles.

14. Ascertain the immediate outcome and long-term prognosis

The nature and pathophysiology of variable types of neurosurgical disorders may not help the neurosurgeons to ascertain an accurate predication of the prognostic outcome for a specific patient. Sometimes predictable answers can be hard to attain. This unfortunately is not rare which complicates the discussion, communication, and the relationship between a medical team and the patient and patient's family. Agonized and apprehensive extremely worried families are eager to hear answers to their painful questions. It is vital to reach the right diagnosis. Right diagnosis is always the fundamental base for management of the patient, however, in pediatric group may not give an accurate predication for long outcome. Usually the families regardless of their age, culture, religion, or race have many very similar nagging and worrying questions regarding the survival and well-being of their loved one.

Effective communication with patients and their families to discuss every step of the management and the prognostic information to the family is very important to create a good relationship and trust between the treating teams and patients and patients' families. The effective communication has profound influence on decisions regarding goals of care and clinical management of the patient, especially when prognostic information is clouded with a confusion of uncertainties [18].

15. Conclusion

Modern medicine may be based on EBM, which is a positive aspect of modern medicine; however, medicine since its inception, thousands of years ago, is based on values. The core of values-based medicine (VsBM) is creating a status to provide the patients the best possible available treatment within a frame of ethics and values which appreciate their culture and keep their dignity. Evidence-based medicine is, and should be, based on ethical and clinical principles which permit the best proven method of management. Values-based medicine and evidence-based medicine are and should be integrated, complementary to each other, not conflicting. The holistic approach to a human who has a disease needs to be treated, not just the disease should be treated. Humanity comes first, always.

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