

Scientific Study Principles, Ethics and Evidence-Based Medicine

Bilimsel Çalışma İlkeleri, Etik ve Kanıta Dayalı Tıp

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Abstract: *Since the beginning of humanity until the present time, the discipline of medicine is in the area of the profession, of which is the object and subject is human, both embraced and violated ethical virtues in practice, and the rules are made for. At this aspect, it is expected that physician is acknowledged about the principles of scientific research with publication ethics and reflect to the applications. It is observed that the violation of the principles of scientific research with publication ethics is mostly originated from the lack of knowledge about these values. Researcher's value system is at least as important as competence. We aimed to emphasize most important aspects stringent for the scientific researches.*

Keywords: *Scientific study principles; ethics; evidence-based medicine*

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Özet: *İnsanlığın başlangıcından bugüne nesnesi ve öznesi insan olan hekimlik mesleği, uygulamada etik kuralların benimsendiği, araştırmalarda etik dışı davranışların en çok göze battığı ve kuralların getirildiği alandır. Bu bağlamda hekimin araştırma ve yayın etiği ilkeleri açısından bilgilenmesi ve uygulamalarına yansıtması beklenir. Araştırma ve yayın etiği ilkeleri ihlalinin çoğu kez bu konudaki değerlerin bilgisizliğinden kaynaklandığı gözlenmektedir. Araştırmacının uzmanlık alanında yetkinliği kadar değer sistemi de önemlidir. Amacımız kanıta dayalı bilimsel araştırmalarda uyulması gereken ilkeler ve önemli etik noktaları vurgulamaktır.*

Anahtar Kelimeler: *Bilimsel çalışma ilkeleri; etik; kanıta dayalı tıp*

INTRODUCTION

Science is a method of approach to definite and documented information. Medicine is not conceptually one of the basic sciences. Medicine is a practical scientific event, besides being a profession and art. It utilizes science in all of its' departments. Even though the purpose of medicine is not to develop science, plenty of scientific invention was developed by physicians. From this aspect, medicine is being influenced by science and influences science (1).

The investigative part of the scientist, emerged with the scientific part of the physicians makes them necessary to research and demonstrate its results via publishing. In this regard, it is expected from the physician to get knowledge for the principles of research and publication ethics and reflect them to practice. The value system is as important as the researcher's competence in the field of expertise (1). The scientific method has a proper ethic, securing an unbiased, straight and logical result. The violation of research and publication ethics frequently shows it is originated from the lack of knowledge about these aspects. We aim to highlight the most important points to be followed in scientific research.

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SCIENTIFIC STUDY PRINCIPLES AND ETHICS

Researches qualified for the conditions necessary for being scientific can be defined as “Scientific” (2). Ethics, derived from the Greek word “Ethos”, can be simplified as “Moral doctrine” or “theoretical morality”; is a mental effort analyzing what are the concepts “good” and “evil”, existence of “absolute good” and “absolute right” and the accessibility to these virtues since the age of Ionian philosophers (2).

From the beginning of humanity until the present time, the discipline of medicine is in the area of the profession, of which is the object and subject is human, both embraced (The Oath of Imhotep 3000 BC, Hippocratic Oath) and violated (Dr. Joseph Mengele in Nazi Germany) ethical virtues in practice, and the rules are made for (The Codes of Nuremberg). From this aspect, it is not wrong to say the source of bioethics is the discipline of medical ethics (1).

The scientist, described by the Turkish Academy of Sciences’ (TÜBA) 14th April 2001 dated announcement in the chapter titled “Ethics in Scientist and Scientific Activities”. It is described as: “The scientist accepts scientific merit as the key criterion at the whole stages of his/her academic life and tasks regarding educational, administrative and academic analyses; doesn’t go beyond basic ethical principles and doesn’t permit of violation of these principles. Insufficient education, copying, violating scientific merit conditions, showing favor to a specific person and similar behavior during academic progress and award jury is intolerable.” (1).

Medical scientific researches whose subject is the “living”, must be designed more detailed and sensitive at ethical aspects. The multi-sided impacts of the studies must be considered by researchers. Most of the ethical problems occurred at scientific researches and the stage of publications arises from ignorance and ill-disciplined study (3). The personal ambition of rapid rising in the institute or academic environment, the desire of being known as famous and successful by other people, the desire of name seen in headlines (Hollywood Syndrome), exaggerated and unproportioned oppression of the institute (demand for the projects being financially supported, etc.), feeling of “more publishment = more prestige”, avarice and sometimes personality disorders are among the possible factors of scientific deception and falseness (4). For that reason most researchers use scientific diversions. The common forms of scientific deception are described and classified by Ruacan (4).

Basics of Scientific Diversion (4):

Authorship right issues: It is described as the situation of names with no authorship right being shown as an author or names with authorship right not shown in a scientific publication. This is regarded as one of the most common forms of scientific deception made in our country. According to the Vancouver System, in a scientific publishment, all of the authors; no matter where they are in the list of authors, are responsible for the study. To become a part of the authors in a scientific publishment, it is necessary to take part in the planning, designing, analysis, and contributing to the interpretation, preparation, or correction of the study. It is obvious that the condition “persons with no authorship right are among the list of authors and persons with authorship right not among the list of authors” does not suit the notion of scientific morals and justice.

Plagiarism: is the term representation of another author’s previously published article wholly or partially as one’s very own original work without referencing. It is decreasing because of the easy accessibility to publishments in all languages via electronic devices.

Fabrication: It can be defined as the publishment of unsubstantial data and results. This way is commonly used because of the oppression of publication from the academic environment.

Duplication: Publishment of same data and results in multiple publications. Publishment of the same publication in different languages is also an example of duplication.

Salamization: Authors trying to artificially divide results from a single study, to broadcast multiple publishments.

Disrespect to Human-Animal Ethics: All researches have to get the approval of the ethics committee for the acceptance requirement. Otherwise, there is no possibility of publishment of researches made on humans and animals.

Biased Selection of References: It is a form of scientific deception made consciously or unconsciously. If the authors just select the references supporting their results and ignore the counter results it will become a biased publication.

Biased Publication (Conflict of Interest): In the present huge amount of financial resources are required for scientific studies. Studies supported by commercial corporations must be clarified that conducted and concluded with scientific neutrality and declare no conflict of interest.

The most important point to be followed in scientific research is the accuracy of the data. Thereby studies will always progress to better. It will also be more efficient for both researchers and societies.

There are many legal regulations for medical researches. These are; Nurnberg Laws (1947), UN Universal Declaration of Human Rights (1948), WMA Declaration of Helsinki (1964), UNESCO Universal Declaration on the Human Genome and Human Rights (1997) and European Council OVIEDO Convention, European Convention on Human Rights and Biomedicine (1,5).

Ethical principles, which establish a start point for the texts of international declarations specific to medical research, are based on protecting the rights of the subjects such as “do no harm”, “respect”, “privacy”, “informed consent”. Principles guide us by instructing us about our actions.

First, Do No Harm: It is the principle also known as “Primum non-nocere” (6). The base of this idea is constituted by the concept that even the patient has a chance of cure in the dynamic structure, this chance would be lost and could cause additional harm by the unnecessary intervention of the physician explained by the Hippocratic tradition (7). The condition of subjects who had organ disorders or failures during pharmacological researches can be a good example of this.

Respect: Respect for all living creatures is considered an obligation. The Declaration of Helsinki is also based on the principle of respect for life (8). It is caring for patient’s rights and ensuring participation of patients in the medical decision during a medical intervention. Herewith both the risk of the injury by medical intervention is decreased and patients’ rights within the relationship between physician and patient can be based on (1).

Privacy/Secrecy: One of the main responsibilities of the physician is to protect the subject’s privacy. This has also priority in the texts of physician oaths (9). It is unethical to imply the name and identity of the subject or using visual data revealing the identity of the subject.

Informed Consent: Prospective subjects should primarily be informed about the aim of the study, methods, expected benefits, possible dangers, and ailments that may arise. In addition; they should be informed that they have the free will to withdraw consent and leave the research whenever they want. And then consent of the subject should be documented in writing. Considering most of the studies of medical applications are retrospective, consent should be taken about filed information for utilization in future researches (10).

Physicians always try to base their decisions on the best available evidence. In past, this evidence was based on observational treatment researches and physician’s personal experience. However, with the emergence and increase of randomized controlled trials, reactions to the current view came up. As a result of, evidence base medicine has been developed (11,12).

EVIDENCE-BASED MEDICINE

The evidence-based medicine (EBM) movement is implemented at the beginning of the 1990s by integrating the evidence into the clinical decision-making progress, to perform the most effective treatment for patients. EBM Working Group has been put into practice with a clinical decision-making method that emphasizes investigating the evidence from clinical trials rather than intuition in medical practice (13).

Evidence-based medicine is the condition in which the most appropriate decisions can be made for practically different patients by analyzing obtained systemic symptoms with clinical experience and knowledge of the physician (14). On the other hand, making the right decisions alone requires extreme clinical experience (15).

Evidence-based medicine is determined to optimize the approach to the patient and the diseases by combining the knowledge obtained from clinical experience and clinical studies.

Methods to be known to apply evidence-based medicine:

Creating answerable questions: To put forth the right questions makes the first and the most important step of evidence-based medicine and undoubtedly requires serious experience. A good clinical question should directly focus on the topic itself, should be open and clear, be suitable for searching the literature and determining the appropriate keywords required for it, and should be able to be answered by searching the literature (16).

Sackett et al., indicate a good clinical problem should include four main components acronymed as PICO (Patient/Problem, Intervention, Comparison, Outcome):

- ‘P’ Patient/Problem: How can you define a patient group similar to yours?
- ‘I’ Intervention: Which examination, treatment, or intervention is being considered?
- ‘C’ Comparison: What is the alternative to your planned intervention?
- ‘O’ Outcome-Result: What is your purpose in the result? (17)

Primarily, a good physician must have full self-confidence in this respect. Questions that cannot be answered with this new information have no scientific value on their own (18).

Surveying for the best evidence: A list of keywords should be made, based on the main word forming the clinical problem. To filter the searched sources, appropriate keywords are combined variously and those that do not have relevance to the subject are excluded (19). Usually, PubMed (NCBI), Ovid, ulakbim, and google scholar are used as databases. The ability to reach the best evidence can be maintained by practice such as swimming or riding a bicycle, rather than reading (20).

Evaluating the data obtained according to importance and validity: It is the step in which the resulting literature containing information and evidence is analyzed. Clinical epidemiology and statistical knowledge are required to make this evaluation. There are two important points during the evaluation of evidence; the first is to decide the validity of the evidence, and the second is to identify the importance of the evidence (15).

To put into practice: Physicians, concerning the individual characteristics, fear, and expectations of the patients, combines the results found answerable to the questions of the previous steps, valid, important, and applicable with own experience and use it for the treatment of the disease. Despite we prove all of the obtained evidence is valid and important, the most important part is the applicability of these methods (14).

To increase clinical performance: To seize the day and increase their own and to increase their performance continuously should be the primary goal of every single physician. Clinicians should ask themselves such as “Did I make an answerable question?”, “Did I get the right evidence in a short time?”, “Could I analyze the evidence critically effective?”, “When I integrated the evidence with my clinical experience and the patient’s characteristics and expectations, did I arrive at a logical and acceptable management strategy?” and evaluate

the” process (21). First of all, they should be able to explain their decisions to themselves. And judge whether they can reach more accurate conclusions in time.

Evidence-based medicine practice is a lifelong process of self-learning, to reach the critical information made necessary by patient needs. Being learned and applied should be part of daily patient care (21). To put evidence-based medicine in practice, physicians should be able to use computers and the internet, have the knowledge of clinical epidemiology and biostatistics to be able to criticize the articles, and be able to decide based on these virtues (22).

In conclusion; as physicians we have to publish scientific researches as adherent to the principles of research and publication ethics, neutral and true form. For this reason; we think we have to know the principles of scientific research and ethics in the most correct way. Likewise we should also be aware that we should not shape our daily practice according to the teachings of evidence-based medicine.

REFERENCES

1. Çobanoğlu N. Kuramsal ve Uygulamalı Tıp Etiği, Eflatun Yayınevi, 2009, s.83-87.
2. Arda B, Şahinoğlu P. Tıbbi Etik; Tanımı, İçeriği, Yöntemi ve Başlıca Konuları. Ankara Tıp Mecmuası (The Of Journal Of The Faculty Of Medicine). Vol.48: 323-336, 1995
3. Kansu E, Rucaş, Cumhuriyet, Bilim- Teknik, 11.11.2000, s.4-5.
4. Ruacan Ş. Bilimsel Araştırma ve Yayınlarında Etik İlkeler, Sağlık Bilimlerinde Süreli Yayıncılık-2003, Tübitak Yayınları, 2003, s.47-53.)
5. *Andrés Constantín*. Human Subject Research: International and Regional Human Rights Standards. *Health and Human Rights Journal*. Dec,2018
6. Büken NÖ.Yaşamın Sonunda Klinik Etik Karar Verme Süreci ve Belirleyici Faktörler.*Türkiye Klinikleri J Med Ethics Law Hist-Special Topics* 2016;2(3)
7. Beauchamp TL, Childress JF. Principles of Biomedical Ethics: 4th ed, New York: Oxford Uni. Press, 1994.
8. Robert V Carlson, Kenneth M Boyd, David J Webb. The revision of the Declaration of Helsinki: past, present and future.Br J Clin Pharmacol. 2004 Jun; 57(6): 695–713.
9. Aydın E. Tarihsel ve Güncel Yönden Tıp Etiği. s.83-101.
10. Arda B. “Yayın etiği” iyi klinik uygulamalar, tasarımdan yayına bilimsel araştırmalar, Ankara Numune Eğitim ve Araştırma Hastanesi Yayını.1999 s.149-162.
11. Horwitz RI, Hayes-Conroy A, Caricchio R, Singer BH. From Evidence Based Medicine to Medicine Based Evidence. Am J Med. 2017 Nov;130(11):1246-1250.
12. Rosenberg WM, Sackett DL. On the need for evidence-based medicine. Therapie. 1996 May-Jun;51(3):212-7.
13. Djulbegovic B, Guyatt GH. Progress in evidence-based medicine: a quarter century on. Lancet. 2017 Jul 22;390(10092):415-423.
14. Demirkan A, Ekici Y, Uçar K. Semih Başkan. Kanıta dayalı tıp. Ankara üniversitesi tıp fakültesi mecmuası Cilt 53, Sayı 4, 2000 221-225
15. Sacket DL, Richardson WL. Evidence Based Medicine. Curchill-Livingstone, London: 1997
16. Akobeng AK. Principles of Evidence Based Medicine. *Arch Dis child* 2005;90(8):837-40.
17. Virgilio RE, Chiapa AL, Palmarozzi EA. Evidence-Based Medicine, Part One. An Introduction to Creating an Answerable Question and Searching the Evidence. *J Am Osteoath Assoc* 2007;107(8):295-7.
18. Terence JR. Need for Evidence Based Medicine, 6,h European Conference on Advences in VVound Management 1-4 Oct. 1996 Amsterdam: 1-3.
19. Babaoğlu MÖ, Yaşar Ü, Dost T. Kanıta Dayalı Tıp: Kavramlar, Örnekler ve Görüşler. *Türkiye Klinikleri J Med Sci* 2009;29(5):1298-305.

20. Zoccali C. Evidence Based Medicine: The Clinicians Perspective, *Nephrol Dial Transplant* 1999; 14 Suppl.3: 42-45.
21. Huic M. Evidence-based medicine and clinical practice. *Acta Medica Academia* 2008;37(1):29-37.
22. Kumar S. Evidence-based medicine: The new paradigm of clinical decision making. *Indian J Urol* 2000;17(1):73-8.