

Ethical aspects of pharmacogenetics: a need for creativity

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The article attempts to reveal the need and issues of creative application of pharmacogenetics in physician's work. Creativity is interpreted based on the concept proposed by Guilford (1971). The proposed major thesis is the following: pharmacogenetics contributes to the implementation of creativity in pharmacotherapy, but its use is limited in today's medical practice. The minor thesis arises from the major thesis: application of pharmacogenetic in everyday pharmacotherapy contributes to the realisation of biomedical ethics principles in personalised medical and individualised personal care, but multifaceted problems arise in the social reality. Scientific sources and texts reveal that ancient ideas (by Plato, Socrates, Aristotle and Hippocrates) are preserved and integrated into the philosophy of modern pharmacotherapy and principles of biomedicine ethics. The development of personalised medicine and individualised care requires creativity both in the science and in the art of medicine, but encounters a collision of biomedical ethics principles and challenges of interpretation. In accordance with the tradition of Hippocrates, it is important not only to adhere to the principles of biomedical ethics, but also to overcome the challenges of consumer society and market economy in today's social reality.

Key words: pharmacogenetics, creativity, beneficence, nonmaleficence, justice, physician

INTRODUCTION

The concept of creativity is multidimensional and varies among various cultures and historical periods. Creativity is the ability to create something new, indicating the generation of original

and meaningful ideas by a person or a group of people (Howkins 2010). Guilford (1971) tried to distinguish the characteristics of creative thinking: fluency, flexibility, originality of thinking, the ability to change one's approach, attitudes, level of detail of the ideas, sensitivity towards the creative problem. Various aspects of creativity were recently analysed by Kačerauskas (2012; 2013a; 2014a; 2014b; 2014c; 2015), Barevičiūtė (2014), Černevičiūtė, Strazdas (2014), Juzefovič (2013, 2015), Aglinskas (2014), Lavrinec (2014), Mitkus (2013).

Antiquity medicine was inseparable from creativity since antiquity medicine is called both an art and a science. Rene Jules Dubos (Park 2002) stated that "ancient medicine was the mother of sciences and played an important role in integrating the early cultures". In assessing the evolution of the idea of medicine, the tradition of Hippocrates reveals the concept of medicine as an art (Clark-Kennedy 2014). The art of medicine cannot be evaluated using the same criteria used for painting or sculpture. Aristotle stated that "the purpose of the art of medicine is health" (Aristotle 1094). Even a cosmetic surgeon, who values the aesthetic effect in his daily practice, does not hold this factor as more important than patient's health. Warsop (2002) states that a cosmetic surgeon is not a creator, treating his patient as a material, like a ceramist uses clay. Similar boundaries for the application of art in medicine are applied by the Christian ethics, stating that any human is a person, created in God's own image. Therefore, each human possesses unparalleled personal value and dignity, forbidding to use him as a means or material for experiments. "So act as to treat humanity, whether in person or in that of any other, in every case as an end withal, never as means only", as the practical imperative of Kant similarly affirms (Kant 1949). In the context of medicine as both science and art this end is nothing but health of a human being.

CONCEPT OF CREATIVITY IN MEDICINE ACCORDING TO THE ANCIENT THINKERS

The impact of the tradition of Hippocrates on medical art is really great. To begin with, this tradition refused to explain diseases on the basis of mythological causal relations and started to thoroughly observe, analyse and describe various cases of illnesses (Clark-Kennedy 2014). At the time of Hippocrates, in order to understand the processes, especially in situations where scientific knowledge was lacking, creativity was extremely important – a physician had to think in a fluent, flexible and original way, to accomplish the treatment plan, to be able to change his opinion if the chosen way of treatment did not help the patient, and, finally, to try to grasp the very essence of the problem. Nevertheless, creativity had its own boundaries – within the framework of the Hippocratic tradition the physician had to follow ethical principles, based on the philosophy of Socrates and Plato, which also remain relevant nowadays. One of its main principles is the classical concept of four virtues. According to it, in medicine, as well as in any other activity, it is necessary to observe four essential virtues: wisdom, courage, moderation and justice. Practical wisdom, or prudence, is an ability to find suitable means for the existing problem. This virtue stimulates creative searches. In the context of medicine it is finding the most effective method of treatment and remedy to cure the given disease and restore or at least improve health of the patient. Practical wisdom is as well a certain caution and carefulness warning about dangers of immoderate experiments and permanent searches of new aggressive modes and means of treatment as well as dangers of hasty application of those modes and methods. Hence, prudence affirms that experiments must be well-founded and purposeful. In the context of medicine courage, on the contrary, urges not to be afraid of experiments, to take responsibility (especially in extreme cases) to seek new, sometimes even aggressive, modes and means of treatment. However, such courage always needs to be cautious, based on tenable knowledge and well-founded

decisions, so it must be consistent with the virtue of practical wisdom. The virtue of moderation demands the process of treatment to be proportional, balanced, and that the drugs must be prescribed in reasonable doses and with reasonable frequency. Meanwhile, justice in antiquity was understood as retribution – giving everyone the goods that he deserves. In the context of medicine it means “rewarding” the disease with the most effective measures and methods of treatment. Searching for them creativity is an obligation. However, the courage of this search should not break the principles of prudence, caution and moderation, because new measures are sometimes less efficient than older ones, sometimes even more harmful.

Aristotle, who divided philosophy into theoretical, practical and auxiliary, distinguished ethics as an area of practical philosophy, concerned with the principles of moral behaviour and activity. One of the core concepts of Aristotle is the concept of virtuous activity as a middle road. Virtue, according to Aristotle, is the golden mean between two extremities or vices – a lack or an excess. This concept also applies in the context of medicine. According to it, the treatment should also aim for the middle. It should be evaluated, wise, cautious and careful striving for health, evading both negligent, careless healthcare (i. e. a lack), and excessive and overboard patient care. On the other hand, this middle road in treatment does not remove the requirement for creativity in the art of medicine, according to Aristotle, “agents themselves must in each case consider what is appropriate to the occasion” (Aristotle 1104), in other words, to find a method or device for treatment, suitable for certain circumstances, by understanding the core of the problem.

Therefore, in the ancient times the concept of treatment as both a science and an art was inseparable from the requirement of creativity, which in turn had to be realized within the boundaries of certain ethical and philosophical principles. As a result, even during the times of Hippocrates the society formed an image of the physician as a counsellor, philosopher and a friend, who patients refer to and who is necessary for even a healthy person (Clark-Kennedy 2014). The art of medicine was and is understood through its application – improvement and strengthening of health and not through its aesthetic result. Goldman and Dennis (2004) believe that without medical ethics, the application of modern medical science is sub-optimal, not useful and even harmful. However, the science and the art of medicine should not be opposed. Creativity in medicine manifests both in the art, and in the science of medicine. Creativity in science can be perceived as a brain storm of ideas, which are later selected and the inappropriate ones are dismissed. Saunders (2000) says that “the art is not merely part of the “medical humanities” but is integral to medicine as an applied science, which requires what he calls a “doctrine of standard empiricism”” (Saunders 2000). It is described as a method of research, which promotes “objective knowledge and truth”, explains and improves understanding (Panda 2006). But only objective knowledge cannot solve the patient’s problem – he lives in a society, possesses personal and cultural values, psychological properties and a view about himself and the world. Therefore, patient’s treatment or health improvement is possible not only by invoking the so-called evidence (which change over time, some theories are dismissed, some are confirmed), but it should be selected and recommended in the aforementioned context. Hence the modern art of medicine is impossible without the advance of science in the same way that the science without the art of medicine cannot guarantee the strengthening and preservation of patient’s health.

PHILOSOPHICAL-ETHICAL BASIS OF TREATMENT

One the most common medical influences on a person is pharmacotherapy – treatment using drugs. Even though it is not noticeable or fully realized, the technical action itself – the

prescription of a drug – is chosen in the society based on certain philosophical-ethical basis. Treatment of patients is based on the principles of utilitarianism and deontology. The deontologic position brings up the principle of the best possible treatment as the duty of every physician. The boundaries of this position require an optimal treatment (and the most suitable drugs) to be found and applied to every specific patient or such treatment at least should be sought. Meanwhile, the utilitarian position takes into the account the fact that because of limited resources (scientific knowledge, methods of treatment, technique, technology, drugs, the quantity and quality of human resources) it is not possible to provide an optimal treatment to every patient. A physician could be Hippocrates (the benchmark of a human physician), but he cannot be Aesculapius (ancient Greek God of Medicine) – his abilities are limited. The optimal treatment for every patient is an ideal, but in reality a different principle should be followed – the best treatment for the greatest number of patients (this principle flows from the core principle of utilitarianism, which summarises various versions of utilitarianism and sounds like this: greatest happiness for the greatest number).

From the historical perspective, decisions about which treatment is best for the patient were made using different paradigms. Until 1992 medicine based on the opinions of authorities was popular – professors and experienced clinicians decided which treatment was best. From 1992 the development of the idea of evidence based medicine began. The best treatment was determined not by the opinion of a clinician, but by performing randomised double-blind trials and by summarising the results. However, this method determines which drug or method of treatment best suits the greatest number of patients and causes them the least adverse reactions. This method does not explain how to treat a particular patient. Therefore, since 2007 the development of the idea of personalized medicine started.

While the aforementioned concepts of medicine evolved in within the boundaries or deontological or utilitarian paradigms, personalised medicine is based more on personalism. Proponents of this relatively new 20th century ethics movement state that of all the objects in the world, only humans, who possess self-consciousness, self-awareness, self-knowledge and conscience, are persons – creatures with free will, dignity and unparalleled worth. These personal dimensions reveal themselves through his/her individual self, which is exclusive, unique and incomparable. The uniqueness of a person requires a corresponding behaviour towards him – communication should be respectful and consider personal character, temperament, physical and intellectual properties, social skills, etc. Treatment of a person as a patient (and the selection of drugs) is no exception – it also should be personalised, should not violate personal dignity, freedom, should consider personal individuality, genetic uniqueness and should allow the person to participate in the decision making for his treatment.

CREATIVITY IN DRUG THERAPY – THE ORIGINS OF PHARMACOGENETICS

This article is based on the cases of drugs used for cardiovascular diseases. Despite the abundance of drugs used for correction of this disorder, the results are moderate – less than 50 percent of cases are able to achieve optimal blood pressure (Johnson 2012). It is found that prescribed drugs benefit the majority of the patients, but among those who are benefited by the drug there are also patients, who experience adverse reactions to the drug, therefore these patients discontinue the use. In addition, for some patients the same drug is ineffective and for another it is even toxic. A creative approach to the problem of inefficiency of the treatment gave birth to a new area of biomedical research – pharmacogenetics. Pharmacogenetics is a science investigating how genetic differences affect the physiological response to the drug

from absorption and metabolism to the pharmacological and therapeutic effect (Lesko 2004). The development of personalised medicine and individualised personal healthcare is possible because of pharmacogenetics. Even though this idea was born in the beginning of this century, characterised by the fastest evolution of science and technology, often the ideals cannot be realised because of limited resources and different philosophies about the distribution of those resources.

The **major thesis** of this article is the following: pharmacogenetics contributes to the implementation of creativity in pharmacotherapy, but its use in today's medical practice is limited. The **minor thesis** arises from the major thesis – application of pharmacogenetics in everyday pharmacotherapy contributes to realisation of principles of biomedical ethics in personalised medical and individualised personal healthcare, but multifaceted problems are faced in the social reality.

The **tactics of the article** (development of the minor thesis) is dictated by the strategy (major thesis): pharmacotherapy will be discussed as an aspect of creative activity of medicine. It will be analysed in the context of the idea of personalised medicine and individualised healthcare. Tom L. Beauchamp and James F. Childress's principles of biomedical ethics (beneficence and nonmaleficence), which continue the tradition of Hippocrates and the idea of justice, will be used.

PRINCIPLE OF NONMALEFICENCE

The Hippocratic Oath consolidates the duty to not harm the patient (lot. *Primum non nocere*), along with the principle of beneficence: "I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them" (Beauchamp, Childress 1983: 106). The principle of nonmaleficence is recognized both in deontological and in utilitarian theories. For example, Hart (1961), a representative of utilitarianism in jurisprudence and ethics, states that the main requirements for rights and morale mostly cover not the active provision of services, but express the negative forms of prohibitions, the most important of which in our social life restrict violence through killing or bodily injury. The duty of nonmaleficence is also formulated in the works of deontologists, like Ross (1930) "The Right and the Good", where it is distinguished from the duty of beneficence, and Rawls (1971) "A Theory of Justice", where it is distinguished from the duty of mutual aid.

The principle of nonmaleficence is often associated with the terms "harm" and "injury". Even though these terms can be interpreted in both physical and psychological area, speaking about treating patients with drugs, they usually refer to physical harm – iatrogenic disturbance of health. Nowadays, the treatment of patients is usually based on the paradigm of "Evidence-Based Medicine". This concept is used since 1992 (Sheschia, Young 2013; Evidence-Based Medicine Working Group 1992) and was introduced as an opposite for the "authoritarian (opinion-based)" attitude, where decisions were made based on the opinion of an authority (Evidence-Based Medicine Working Group 1992; Straus et al. 2011). This paradigm is characterised by a hierarchical system, where various research methods are grouped by levels of evidence. For example, non-randomised clinical trials occupy a lower place in the hierarchy. In this hierarchy there is no microbiological, pharmacological, biochemical and physiological research, the results of which are important in the studies of drug efficiency (Feinstein et al. 1997). In addition, randomised clinical trials do not provide answers about long-term effects of the drug and about undesirable reactions to the drug; they provide means and medians – information about the short-term effect on the average patient. Buchanan and

Kean (2001) state that “patient is not a mean or median”. Also, certain statistical measures, such as “number needed to treat” and “number needed to harm” indicate that investigations of treatment methods are oriented towards the relative risk of harm avoidance – the lower the number of harmed patients, the better the drug. However, a physician, prescribing the drug, does not know whether he will help or harm a specific patient – the patient might be the only one from N number of cases, whom the drug harms and does not help. In this case physician’s creativity is important in making an individualised decision. A physician cannot follow only recommendations – according to Guilford, if he wants to minimise the risk, he must quickly evaluate the clinical symptoms and propose ideas about the changes in patient’s body, change his opinion about the treatment of a specific patient, think outside of the box, and most importantly he must be able to realise the core of the problem – evaluate the genetics of the patient and not prescribe the drugs, which might harm him. This method is already applied in oncology, but not among patients with cardiovascular diseases. Unfortunately, genetic analysis of every patient is still a thing of the future of medicine. Because of limited resources and novelty of the science (pharmacogenetics), a physician cannot possess all of the information, so there is a great need for creativity, in order to fulfil the Hippocratic Oath.

PRINCIPLE OF BENEFICENCE

A physician, following the Hippocratic tradition, not only must not harm but should also follow the principle of beneficence. Beneficence is understood not only as abstaining from improper actions but also as an active effort for the benefit of the patient (Beauchamp, Childress 1983: 149). One example is treating the patient based on his genetics, using a method of treatment, more effective than other alternatives. A modern physician, aiming to adhere not only to the principle of nonmaleficence but also of beneficence, in his daily practice must employ a creative view of the recommendations based on evidence. His purpose is to help a specific patient, therefore unconventional thinking and realisation, that there are no absolute truths in medicine and all patients cannot be described by standards, is the core of a creative medical practice. However, in this context a physician encounters a dilemma – with a lack of final and undeniable evidence he cannot know for sure what is best for a specific patient. Statistical calculations show what is effective or not harmful to the majority, but how can one reasonably suspect, before harming the patients’ health, that he will react to the drug differently or that the drug is ineffective in the long term?

PRINCIPLE OF JUSTICE

A physician, both as an artist and as a scientist, is forced to search for a solution of the situation because of the development of the consumer society. The pharmaceutical industry is oriented towards profit, which can be obtained in a large market – it is worthwhile to search for and sell drugs that will be mass-consumed and it is not worth investing in research that will only benefit people with a certain genetic variation. Therefore, this collision hinders the advance of pharmacogenetics and poses questions about targeted selection and exclusivity (only the patients with the most common genetic variation are treated). Such situation could be justified by the evolutionary (sociobiological) ethics, based on the universal principle of natural selection – it is worth treating only the most adapted people, i. e. the ones, who possess the most common genetic variation. On the other hand, a question arises how acceptable is the aforementioned principle in the art of treatment, which has long been altruistic? Moreover, a discussion arises what is the concept of justice, i. e. which model of treatment is just on the whole? Beauchamp

and Childress (1983), while describing the principles of biomedical ethics, introduced Rawls' concept of justice – equal distribution regarding finances by ignoring individual characteristics. Therefore, the same amount of money should be spent on treating each patient. This way the applied standards will mostly help individuals with the most common genetic variations (the majority is privileged against the minority). Utilitarian theories state that it is right when the benefit for the society and an individual is the greatest.

Meanwhile, egalitarian theories state that it is right when during his life a person receives everything a rational person could want. Health is the greatest asset; therefore, in the context of these theories, it is right for a person to receive the optimal treatment. Pragmatist theories highlight the needs of the society (as well as the individuals that it is made up from). Health is also one of the basic needs of every society; it will only be maximally satisfied when the treatment meets the needs of the members of such a society. Actions of individual people are highlighted by ethic individualism theories. According to individualism and pragmatism it is right when treatment is prescribed according to the needs (of the individual and/or society). The most effective, least harmful treatment for a specific patient meets his needs. If the resources were unlimited, the treatment which meets personal needs according to genetics would meet both the needs of society and personal interests. However, treatment according to needs and desires is very expensive (Beauchamp, Childress 1983). In this case, the minority, whose diagnosis or treatment receives more resources, will be privileged over the majority of the patients.

The argument of limited resources is often employed when speaking about individualised care and personalized medicine. But in modern medicine there already are examples, where treatment is prescribed while taking into account genetic variations, mostly in oncology. Speaking from the perspective of the justice principle, individuals suffering from cardiovascular diseases are being discriminated against by disease categories. Therefore, in applying treatment for patients, suffering from cardiovascular diseases, the main role should be played not by limited resources, but by the advance of science, system of values and development of creativity. Therefore, by evaluating the ethical aspects of use of pharmacogenetics, we can state that differentiation of patients according to genetic variations would help to implement the principles of nonmaleficence and beneficence and would not contradict the principle of justice in medicine, but the creativity of scientists and government representatives is required for the costs not to be an inhibition of the development of personalised medicine.

CONCLUSIONS

Based on the ancient thinkers, we can state that medicine is both a science and an art, and the creativity in medicine is the strengthening of personal health by realising the Hippocratic tradition – the principles of nonmaleficence and beneficence. Pharmacogenetics, as a new area of medicine, contributes to the development of individualised personal care and personalised medicine and can help avoid or reduce the harm, caused by use of inappropriate products, or to determine groups of patients, which will receive the most benefit from the consumption of a certain drug. Creativity is an obligation in the science and art of medicine, while striving to apply the achievements of pharmacogenetics. However, one should not only adhere to the principles of biomedical ethics, but also overcome the challenges of consumer society and market economy in today's social reality.

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Farmakogenetikos etiniai aspektai: kūrybingumo poreikis

Santrauka

Straipsnyje bandomas atskleisti kūrybingo farmakogenetikos taikymo gydytojo darbe poreikis ir problematika. Kūrybingumas interpretuojamas remiantis J. P. Guilfordo (1971) pasiūlyta koncepcija. Iškeliama didžioji tezė: farmakogenetika prisideda prie kūrybingumo farmakoterapijoje įgyvendinimo, tačiau ribotai taikoma šiuolaikinėje medicinos praktikoje. Iš didžiosios tezės išsirutulioja mažoji tezė: farmakogenetinių tyrimų taikymas kasdienėje farmakoterapijoje prisideda prie biomedicininės etikos principų įgyvendinimo personalizuotoje medicininėje bei individualizuotoje asmens priežiūroje, tačiau socialinėje realybėje iškyla daugiaspekčiai sunkumai. Remiantis moksliniais šaltiniais bei teksta atskleidžiama, kad antikos mintis (Platono, Sokrato, Aristotelio) ir gydytojų veiklos pagrindinės idėjos (Hipokrato) yra išsaugotos ir integruotos į modernios farmakoterapijos filosofiją bei biomedicinos etikos principus. Personalizuotos medicinos ir individualizuotos asmens priežiūros plėtra reikalauja kūrybingumo tiek medicinos moksle, tiek mene, tačiau susiduria su biomedicininės etikos principų kolizija ir interpretavimo iššūkiais. Plėtojant Hipokrato tradiciją svarbu ne tik laikytis biomedicinos etikos principų, bet ir įveikti vartotojiškos visuomenės ir rinkos ekonomikos iššūkius šiuolaikinėje socialinėje realybėje.

Raktažodžiai: farmakogenetika, kūrybingumas, geradarystė, žalos nedarymas, teisingumas, gydytojas