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The Gap between Bioethics Principlism and Judicial Responsibility: How Social Sciences Can Help Romanian Law

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Abstract

Applying bioethics traditional principles in modern medicine is a difficult process. Alternative approaches compete with the so-called principlism. The law is required to offer solutions that best fit contemporary realities and moral problems, always taking into account the individual and the survival of the medical system. This paper shows how the four principles of Beauchamp & Childress (2009) translate into Romanian law. It argues that social sciences shouldn't be considered from an adversarial position with bioethics. Authors consider that the empirical based psychological and sociological findings are able to fill in the gap between bioethics and an adapted and regulated medical practice. This is true worldwide and especially in Romania, where transition makes the defensive medicine a danger for quality evidence-based care.

Keywords: medical practice, bio-ethical principles, social sciences, legislation, judicial responsibility.

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Introduction

Since Hippocrates' time and onto the mid-20th century, medical ethics has been marked by the tradition of Hippocrates' oath (Porter, 1999). The development of medical sciences raised questions regarding the applicability of traditional moral concepts in the specific context of different communities (Jonsen, 2003). Therefore, a broader sociological engagement with bioethics becomes imperative (López, 2004). The Hippocratic tradition and the application of "primum non nocere" principle can no longer offer modern medicine the appropriate set of moral principles and norms (Porter and Rai, 2009). For instance, problems regarding informed consent, distribution of medical resources, collective and personal responsibility for health, or the use of human subjects for research are neglected by traditional ethics (Beauchamp & Childress, 2001). Although, the principlist approach in bioethics developed in the last decades attempted to provide a sound framework for solving these modern moral dilemmas, many scholars found this approach abstract and proposed a re-conceptualization of the field (Widdershoven, 2002). Principlism has been accused of decontextualizing the ethical decision-making (Hanson, 1999). For instance, most of the arguments developed by using this approach favored patient autonomy over other principles, simply because autonomy is the most valued principle in the US (Gillon, 2003), where this approach has been developed (Baker, 2001). However, by doing so the worldwide distribution of this approach carries with it the transfer of some values in other societies. Therefore, some researchers have proposed an alternative normative approach called the sociology of bio-knowledge which should focus on human rights (Petersen, 2013). On the other hand, there are scholars who argue that sociology can only make a limited contribution to bioethics (Sheehan and Dunn, 2013). The principles, denounced by such multidisciplinary approaches, give the judicial system, the opportunity to elaborate norms, which are applicable to medical practice. The context of modern medicine in Romania requires a framework to analyze health care moral dilemmas, as well as the need to know, interpret, respect and apply the legal regulations.

This paper analyzes the depth of medical responsibility from a moral, social and legal perspective. Moreover, it argues the existence of a case-effect relationship between the two perspectives (moral principles determine judicial liabilities) (Nanu, 2008). The appeal to one's own conscience or moral norms has proven insufficient to align the medical scientific development from the last century to moral values of the humanity. Social sciences can and should contribute to a solution to this major issue. Potter defined bioethics as a new discipline, which reunites biological knowledge and human values system knowledge. We choose bio – to represent biological knowledge, the science of live systems; we choose ethics –to represent the human values system" (Potter, 1970). One can easily see the potential problem in translating this duet into practice. Mass media

takes over many of the bioethics preoccupations and develops them as public debate subjects (Zylinska, 2009). Therefore, the domain is of great interest to the entire society, overcoming this way the boundaries of the medical world. Social sciences can fill in the gap between bioethics solution and the social realities of the everyday life (Borry *et al.*, 2004, De Vries *et al.*, 2006, López, 2004, McInerney, 2000, Petersen, 2013, Sheehan and Dunn, 2013, Weyers, 2006).

The four principles of bioethics

Ethics tries to answer the question: “Which general moral model of behavior evaluation and guidance has to be accepted and why?” Many types of classic moral theories have been used over time by specialists as sources to develop a coherent moral theory -utilitarianism, Kantian theory, and virtue ethics - (Beauchamp & Childress, 2001). However, these theories are to some extent contradictory in nature and cannot easily lead to unitary ethical solutions. Under these circumstances, a new approach (“the four principles” or “principlism”) has attempted to create some level of coherence at the crossroads of the classic theories. It is conceived to express general moral norms, applicable to bioethics (Beauchamp & Childress, 2001).

Moral norms, which represent the foundation of bioethics, are expressed as an analytical structure represented by a set of moral principles. This approach, also known as “the four principles of bioethics”, tries to describe a minimum of moral requirements for health care professionals. The principles described by Tom L. Beauchamp and James F. Childress are recognized by most researchers in this field. The moral framework that principlism adopts is based on common morality of the society (Beauchamp & Childress, 2001), its role being to guide the settling of certain ethical dilemmas (moral issues resulted from daily practice). However, in a multicultural world common morality may not be universal, (Turner, 2003) and, therefore, by applying blindly arguments developed in one society in any other one may led to culturally insensitive solutions. In this way, social sciences can contribute with empirical findings to culturally sensitive ethical solutions (Borry *et al.*, 2004). Principlism recognizes four principles: Respect for autonomy, Non-maleficence, Beneficence and Justice (Beauchamp & Childress, 2001). The non-maleficence and beneficence principles have found their justification in the traditional Hippocratic medical ethics, whereas autonomy and justice contribute to enlarge traditional approaches. Following we briefly review the four principles before discussing how they transpose in laws.

Respect for Autonomy

The word autonomy derives from the Greek “αυτος” (own) and “νομος” (rule, law). All autonomy theories recognize two essential conditions: the independence from controlling influences and the capacity to initiate intentional actions (Miller, 1981). Respect for autonomy supposes that individuals know their right to have an opinion, are able to make decisions, have the capacity to reflect on their actions and to act in a way consistent with their personal values and beliefs. In medical practice, this principle is translated via informed consent, which attempts to provide competent persons with reasonable information that could enable them to make voluntary and informed medical decisions (Miller, 1981, Beauchamp & Childress, 2001).

In the literature concerning medical practice, the informed consent is significant in two ways (Beauchamp & Childress, 2001). First, informed consent deals with patients’ autonomous consent for a medical intervention. Second informed consent has to abide to social rules of consent, meaning that patients must give a valid agreement, both legally and institutionally, before initiating any diagnosis, treatment intervention. Beauchamp & Childress suggest seven components for a reasonable informed consent: competence (the ability to understand and decide), voluntariness (making decisions free of coercion), information, recommendations (of a treatment plan), understanding (of the information and the plan), decision and authorization (of the chosen plan). Although autonomy is a characteristic of mentally competent persons, this principle requires health care professionals to protect those with diminished autonomy.

Non-maleficence

Non-maleficence requires medical practitioners to avoid harm as well as the risk of harm (negligence). In modern medicine, non-maleficence is reflected by medical professionals abiding to performance standards usually described in terms of evidence-based medicine (Hope, 1995), which establish what is expected from health professionals, summing up the necessary qualities for medical practice (prudence, diligence, patience, sapience). In addition, the environment where medical care is provided has to enable medical practitioners to provide safe care to patients by providing the required health resources. Thus, non-maleficence involves avoiding unnecessary risks, and, when risk is unavoidable, its minimization as much as possible (Sharpe, 1997).

Applying non-maleficence principle in the context of health care might benefit from the input of social sciences. Especially in difficult dilemmas, the bioethics reflection usually proceeds in three major steps: the description of the moral issue, the assessment of the moral issue and the evaluation of the decision-making process. Empirical research can make a contribution to each of these three steps.

First, empirical research could play a role in answering the “reality-revealing questions”, in assessing the outcomes and in proposing alternative courses of action. Second, empirical research can intervene in balancing inductive normativity and deductive forms of normativity. Third, empirical research can point out certain unexpected consequences (Borry *et al.*, 2004). In these ways, social research could provide the required evidence for ethical decisions in specific social context.

Finally, avoiding harm in modern medicine is represented by predicting the magnitude of the risk associated with a procedure or intervention. Yet, although modern medicine has made significant advances in terms of effectiveness, these medical advances are associated often with significant risks, and doctors as well as their patients have to assume risks in the context of modern medical care. On the other hand, the very notion of patient safety is represented by the magnitude and likelihood of the risks that are deemed acceptable in a particular society. However, the appetite for risk differs from country to country and from community to community (Holm, 1995). Therefore, patients’ safety may not be defined similarly in any given society. Social sciences may significantly contribute with empirical findings to understand what safety and subsequently non-maleficence mean in a particular society.

The beneficence principle

This principle refers to doctor’s obligation to act in the best interest of their patients (Beauchamp & Childress, 2001). Beneficence is more demanding than non-harming principle as it requires doctors to initiate measures, which promote patients’ best interests, not only to abstain from doing wrong. This principle implies the obligation to do good for others and to calculate utility, by maximizing the benefits and by minimizing risks and costs in order to obtain cost-effectiveness (Beauchamp & Childress, 2001). Moreover, it doesn’t represent a source of legal sanction if not fulfilled. It is common in the medical practice to occur conflicts between beneficence and autonomy principles (Beauchamp & Childress, 2001). The idea of benefit, as a primary liability in medical care is ancient. Nevertheless, during the last decades, medicine had to deal with the justification of the patients’ right to freely decide. These duties are obvious in medical practice and accepted as objectives in the medical activity. These objectives apply both to the patient as an individual, as well as to the entire society (Singer, 2011). In the decision-making process, evidence-based medicine might prove useful (Borry *et al.*, 2004).

Justice

The problem of access to medical resources is exacerbated by the significant increase of the medical costs due to pervasive implementation of modern technologies in health care. The idea of justice is, thus, extremely debated and

controversial. All judicial theories are set on the minimal demand attributed to Aristoteles: “the equals have to be treated as equals and the non-equals have to be treated as non-equals” (Gillon, 2003). This principle is called “formal justice” because it doesn’t indicate any criteria to determine whether two persons are equal or not and neither the features of an equal treatment.

National health systems have to deal with the financing and distribution of health resources. Inefficiency of health systems determines increased costs and lack of protection for a great number of persons. Systems have to promote efficiency, as well as equity. Although the two terms do not seem compatible, both are necessary for health systems to function properly. However, by promoting efficiency of the system by reducing health care costs may conflicts with patients’ autonomy. Thus, it is obvious that a compromise has to be taken between autonomy and efficiency (Fleischacker, 2009).

Transposing the four principles into legal norms, applicable to the medical field

The four principles determine rules of behavior in the doctor-patient relationship (Oprea, 2009a). The law transformed this conduct into regulations, which include the civil responsibility of the medical staff and rules for conducting medical research in Romania. Interpreting laws, which are applicable in medicine, are facilitated by the understanding of moral principles on which these norms are based. Therefore, we consider legal regulation as a consequence of applying moral theories. We further analyze each of the principles elaborated by Beauchamp & Childress from the perspective offered by the current law in Romania, applicable both to therapy and to clinical research.

Autonomy principle

There are two types of legal regulations, which reflect this principle: informed consent and confidentiality. It is mandatory that patients are fully informed on the benefits and risks of any medical procedure. The absence of informed consent could result in patients’ abuse. In the context, when a patient is harmed as a result of medical care, lack of previous informed consent may result in health professionals’ civil responsibility. However, failure to provide informed consent is mentioned as an exception in most professional insurance policies for malpractice, so health professionals in this situation become unassisted.

The responsibility of health professionals (defined by the law as the doctor, dentist, pharmacist, medical assistant or nurse) to obtain informed consent is clearly stated within the law: “in order to be exposed to preventive, diagnosis and treatment methods, which have a possible risk for the patient, after receiving the

explanations from the doctor, dentist, medical assistant/nurse, according to paragraphs (2) and (3), the patient is required to give it's written consent (Guvernul României)." Once the necessity of obtaining an informed consent from the patient before initiating any medical act, has been established, the law offers indication about the content of this process. Informed consent has to contain information on "diagnosis, nature and aim of the treatment, risks and potential consequences of the treatment, realistic alternatives, risks and consequences, prognosis of the condition with and without treatment" (Guvernul României). These requirements are completed by the regulations of another law (no. 46/21.01.2003), which mentions: "the patient has the right to be informed on his health status, required medical procedures, potential risks, available alternative therapeutic options, including information about not following any treatment and not respecting medical recommendations, as well as data regarding diagnosis and prognosis (MORAR *et al.*, 2014)." Moreover, informed consent has to contain, according to the law, a brief description of the information that has been given by the doctor, dentist and medical assistant or nurse (Guvernul României). For a better understanding of all the implications of medical interventions patients have the right to be informed, regarding available medical services, as well as on the way to use them. In order to guarantee patients' rights to exercise their free will, the law establishes doctors' obligation to provide data regarding the identity and professional status of the health professionals, as well as the rules, which they have to respect during treatment. The development of scientific research and innovation in medical practice has led to additional requirements. Thus, informed consent is mandatory for harvesting, keeping and using any biological product that will be used in scientific research (Morar *et al.*, 2014).

Analyzing the aforementioned information one can notice two fundamental elements of the law regarding informed consent. Laws attempt to guarantee patients' rights to make autonomous decisions in a way consistent with ethical principle of respect for patient autonomy: "A person acts autonomously when his/her actions are the result of his/her own choice or decisions". It also includes the necessity for doctors to initiate an efficient communication between them and their patients (Sandu *et al.*, 2013). The communication process recognizes two requirements: (a) to provide any necessary information so that the patient can make a sound medical decision; and (b) to assure a clear patients' understanding of the health care context. The foundation of doctor-patient relationship is represented by mutual trust that is built through respecting the patients' right to make a decision regarding their health status and by protecting vulnerable persons that cannot fully exercise their autonomy into health care context (Oprea, 2009b).

Adult persons who have mental competence can express a valid consent. However, this is not the case in children, or in persons who can't exercise consent due to external factors such as a deterioration of their mental capacity. Children can express their consent if their parents are missing, only in emergency cases

and, only if the minor has the necessary mental competence to understand the medical situation. In addition minors over sixteen years old are allowed to make health care decisions regarding their reproductive health. If the legal guardian or the next of kin can't be contacted and patient has no mental competence, the doctor, medical assistant/nurse can solicit the authorization of the medical procedure by the authorities or can proceed without any consent if the time needed to obtain consent would put the health status of the person in danger (MORAR *et al.*, 2014). Under these circumstances, the doctor or the medical team who assumed the decision, have the obligation to write a report and describe the situation which required medical care, reporting elements that attest the emergency situation, as well as data which prove the lack of the patient's mental competence (Guvernul Romaniei).

Taking into consideration the principle of respect for autonomy, some of the legal regulations, regarding confidentiality of data obtained medical care, have to be further analyzed. The doctor can't tell any other person without patient consent, any data regarding his health status. Any information regarding the patient's health status, investigation results, diagnosis, prognosis, treatment plan, as well as any information that could link the identity of a person to some medical information is strictly confidential. Therefore health care professionals can provide information only if he/she has the expressed consent of the patient. Under these circumstances, no information can be given to family members, friends of the patient without the consent of the patient. This may be a significant problem especially in the Romanian context, where traditionally patients' families are involved in the medical decision making without any context (Sandu *et al.*, 2013). This suggests that in Romania, autonomy is understood rather in as relational than as individual autonomy. However, further social research is required to understand what patients' mean by autonomous decision making in Romanian context. The findings may significantly contribute to adapt the law as well as legal and medical practice to cultural context in this country.

However there are some exceptions: First, there is patients' consent to provide information to other people, indicated by the patient himself/herself. Confidential information can be provided only if the patient gave his consent or if the law demands it. Second, the patient can decide not to be informed regarding his health status and indicate another person to receive this information for him/her. The patient has the right to do not know. Third, when information is necessary to other health care providers, obtaining consent is not mandatory. Fourth, if the patient represents a danger for himself/herself or for public health and there is proof, the case is considered exception and information could be disclosed (Morar *et al.*, 2014). Concluding, the law, in concordance with autonomy principle, supports confidentiality with only few exceptions.

However, sociologists might show that the applicability of the informed consent is not always what it seems to be. Not all patients engage in the education

process, which is supposed to accompany a formal informed consent (Jordens *et al.*, 2013). This is a clear and at hand example of how both law and bioethics need social sciences to help in understanding how the autonomy principle really translates in an autonomous consent from the part of the patient.

Beneficence and Non-maleficence

Beneficence requires doctors to act in a way that promotes patients' wellbeing (Beauchamp & Childress, 2001). Non-maleficence requires anyone who provides medical care to do not harm the patient. Both principles are of fundamental importance and subordinated to the patients' interests. However, the simple normative approach residing on the two principles might not be able to explain, by itself, the changes in law (Borry *et al.*, 2004). Some scholars argued that bioethics are simply a part of larger systems of social control and give the example of euthanasia. The debate over laws like voluntary euthanasia might be the result of three social changes: individualization, diminished taboos and changes in the medicine's balance of power between medical staff and patients both at an institutional and individual level. The legal relaxation concerning euthanasia might go together with new ways of social control: doctors' self-control is counterbalanced with patients' control, professional third-party control and control from the state (Weyers, 2006). Questions such as euthanasia and physician-assisted suicide can be considered part of an international social movement called "the requested death movement" (McInerney, 2000). Although the beneficence and non-maleficence principles seem have the same substance (to do well is a way to avoid causing any harm), the difference resides in the way they implicate the medical staff. In the category of the non-harming principle, following secondary principles are included: not to kill, not to cause unnecessary pain, not to determine disabilities (Beauchamp & Childress, 2001). It can be observed that these demands can be fulfilled without any activity (without doing anything). Unlike the non-harming principle, beneficence requires active participation: prevent death, prevent unnecessary pain, and prevent disabilities. Thus, the obligations set by the non-harming principle have to be impartially followed and represent moral sources of legal sanctions. In contrast to all of these, the obligations required by beneficence do not always have to be impartially respected and do not generally lead to legal sanctions if not respected. In order to see how Romanian legislation responds to principal problems, we will further debate the implications in medical practice.

According to the non-harming principle, medical staff has to act in a manner that avoid unnecessary harm (self-harm or harm to other persons), intentionally or not. It doesn't demand the impossible, because the level of knowledge, the power to control the natural evolution of disease, or the uncertainty of results, represent limitations for obtaining this desiderate. Nevertheless, some performance

standards for the medical staff can be set, implying on one hand, prudence, patience, thoughtfulness, and on the other hand, limitation to one's own competence, so that the patient is not exposed to unjustified risks. Romanian legislation has the following requirements. Medical staff responds civilly for any harm caused by the profession if the limits of competence are overstepped. If some associated medical conditions are present, each of them has to be supervised/diagnosed/treated by a specialist/person who is competent ("not to harm" (Guvernul României). The law sets an exception, reserved to emergency situations only, where the necessary medical staff is not available. Under these circumstances one can act even if not in his area of competence, being necessary to prove those cases (to do well) (Guvernul Romaniei). This is how the two bioethics principles complete each other, giving solutions, which are applicable to medical practice respecting both moral and judicial norms. The balance between the two fundamental demands of medical practice (not to harm and to do well) can be disrupted, if the law ignores this problem. The risk can already be seen in many countries with consistent jurisprudence in malpractice. In the US, for instance, the disruption of the two components, leads to the phenomenon also called "defensive medicine". This is described by the Office of Technology Assessment of the US Congress as occurring when doctors solicit tests, visits or avoid procedures or patients with high risks, with the main purpose (but not only) to reduce the danger of being exposed to malpractice accusations. When doctors do tests or oversized procedures in order to reduce the risk of malpractice accusations, they practice positive defensive medicine. In contrast, the practice characterized by avoiding difficult patients or high-risk procedures is called negative defensive medicine" (Hellinger & Encinosa, 2006).

Positive defensive medicine can have unwanted consequences on cost increase for medical services, as well as soliciting tests that are risky for the patient (not respecting non-maleficence principle). Negative defensive medicine has more dangerous implications. The danger is represented by the fact that beneficence is sacrificed in favor of the non-harming principle, adopting a passive attitude (rather not to do anything at all than to do harm) with the purpose of avoiding malpractice accusations. For instance, in the US many medical fields such as obstetrics suffer an acute shortage of doctors, because they avoid the huge costs associated with the insurance policies for this specialty.

The justice principle

According to this principle, every patient has to benefit from an equitable distribution of medical services and health care resources. That is, patients with similar health needs should be treated similarly (Beauchamp & Childress, 2001). General factors that contribute to identifying health care needs are medical (the patient's estimated benefit, the emergency, changes of life quality, period of

maintaining the benefit) and non-medical (paying capacity, social value, treatment difficulties, the patient's contribution to his own health status deterioration, previous use of resources for medical care). These criteria are divided into three categories, on three levels where social justice can act: national, institutional and individual. At a national level, medical health care needs have to be identified, as well as associated costs, and health care rationalized because the economic constraints limit in any society the full coverage of medical care (Botezat *et al.*, 2013). The Romanian law allows selection criteria in cases where access to some medical services/treatment is restricted for financial reasons. Applicable criteria for financial restrictions (programs having limited number of enrolled patients), are established by the Ministry of Health and are only of medical nature (medical criteria to be included in the treatment scheme). At institutional level, restrictions for medical care can be established based on working conditions, internal rules regarding the administrative situation (e.g. An emergency unit cannot refuse emergency care). At individual level, health care professionals have clear responsibilities, with respect to patients' access to medical care. Thus, it is prohibited to discriminate persons, based on race, gender, age, ethnicity, national or social origin, religion, political options or personal dislike (Guvernul Romaniei).

The application of the justice principle is a good example of the supposed adversarial relationship between bioethics and sociology (De Vries, 2004). While bioethics emphasizes the clear descriptions of ethically charged cases provided by social researchers, it doubts the ability of sociologists and psychologists to logically discern "the good". On the other hand, social scholars find bioethicists unable to understand that the elegantly created solutions to ethical dilemmas get altered when transported in various social and cultural settings (De Vries *et al.*, 2006). Seemingly, both sides ignore the gap between them, leaving their separate contribution far less valuable than an integrative gain.

Conclusions

The spectacular evolution of science imposes the necessity of an active debate regarding ethics and morality a real revolution in life concepts, stimulating the reflection on human destiny. Respecting bioethics principles involve the moral responsibility of the health care professionals, as well as the legal one. The medical procedures, as interactions between doctors and patients could be guided by bioethics principles. Each principle finds a correspondence in law, applicable to medical practice, including in Romania. Thus, the context of modern medicine in Romania recognizes the need of a framework to analyze ethical dilemmas by using bioethics principles, as well as the need to know, interpret, respect and apply regulations, under existing circumstances of vulnerability in this field. The bioethics debate, as well as the future changes in laws, will significantly affect

medical practice. The gap between a morally and ethically overdone system to civil, administrative and even criminal sanctions raises problems concerning how the medical practice in Romania should adapt. This is where social sciences can help. By considering the contribution in the decision-making process, the social context of legalization and the social environment of morals, fields like psychology and sociology can and should be present. They can also help facing the danger of “defensive medicine” phenomenon, as a reaction of the medical staff towards the risk of malpractice accusations.

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