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MAIN BIOETHICAL CHALLENGES IN AZERBAIJAN THAT SHOULD BE RESPONDED BY MEDICO-LEGAL SPECIALISTS

The progress of biomedical science and adoption of new technology in the practice of public health determined modern problems of bioethics:

- Patients' rights and bioethical issues in public health (informed consent, privacy/confidentiality, representation, medical errors, medical insurance, etc.);
- Human rights protection (including HIV-infected, mentally diseased, disabled, children and other patients with the limited capacities);
- Justice, equality and accessibility in public health;
- Transplantology and organ/tissue donation;
- Assistance to dying patients (hospice and palliative care);
- Suicide and euthanasia (passive or active, voluntary or forced);
- Legal and ethical bases of death investigation, attitude to corpses;
- Experiments carried out on humans and animals;
- Pharmaceutical business and bioethical issues;
- Abortion, contraception, status of embryo and new reproductive technologies;
- Modern genetics (gene diagnostics, gene therapy and genetic engineering);
- Manipulation of stem cells;
- Cloning (therapeutic and reproductive);
- The medical aspects of human rights; influence of human rights deteriorations to health status;
- Influence of new technologies on ecology and environment.

Few most important bioethical problems for Azerbaijan now which are also related with forensic medical activities it is better to stress as ethical challenges must be responded during next years:

A. Patients rights and bioethical problems of public health, including informed consent on medical intervention, privacy/confidentiality matters and medical errors. We strongly believe that experts in forensic medicine and medical law may contribute a lot to develop below mentioned directions of the problem.

Just as human rights lie in the basis of democracy, in the middle of health care system should be patient rights. In other words, it is possible to judge about observance of human rights by the extent of approaching or moving away from democratic principles. The same relates to patient rights. They must be chief in healthcare. In their basis lie hard, delicate and confidential relations between a physician, medical system and a patient. Since 1970-s understanding of necessity to adopt laws about patient rights has been growing. For the first time, a patient was fairly put into the centre of the whole system of health care due to developed at that time Stockholm model of health care. European Union adopted "Charter of the patients' rights in hospitals" in 1979, and European Parliament decided to start its development in 1984. In 1997, EU adopted "Convention for the protection of rights and dignity of the Human Being" in biology and medicine that came into effect in 1999. In fact, this was the first international and compulsory document about citizen rights in health care. In 1999, Council of Europe adopted Recommendation for the protection of rights of the mentally ill etc.

On the other hand, just as a patient must have his rights, including a right to independence, a physician must have specific rights along with rights to intellectual property and independence. That is why it is reasonable in addition to adoption of the law about rights and responsibility of a patient to adopt the law about rights and professional responsibility of physicians and other medical workers, including insurance of risk during professional medical activity. The way to protection of patients' rights lies through legal enlightenment of citizens and through development of medical law. New scientific area – medical law - quite new to the legal system of Azerbaijan and must be developed. Forensic – medical specialist may play active role in this

process. Teaching this subject must be obligatory not only at the medical faculty, but also at the faculty of law. Only in the junction of these two specialities it is possible to achieve development of this area. It is new to our country, but existing for a long time in the world. Development of the legal profession in our country, including medical law, will give an opportunity of establishment new generation of experts able to protect rights of citizen in healthcare.

Informed consent on medical intervention. A physician must secure patient's consent to intervention, in case of his incapacity – consent of his representatives; must formalize de jure this agreement. According to Azerbaijan present legislation consent should be taken, but the written form of patient's consent to medical intervention is not obligatory that creates many problems in the negative outcomes of the treatment. If patient's condition does not make it possible to express his will, a physicians' concilium settles the matter about urgent medical intervention. If it is found impossible, the decision is made by the doctor in charge on condition of further notifying the officials of medical-prophylactic institution. The same tactics is considered competent during treatment of children less than 15 years of age and incapable persons, when physicians do not have any possibility of getting consent from their legal representatives.

The informed consent to medical intervention is necessary for legal guarantee of medical activity. The written form of the informed consent to medical intervention is a more competent option for a medical institution as well as for a patient when proving his case in the course of the assize. In addition, it disciplines physicians while carrying out medical intervention. The written form should be kept with patient and in a medical institution. Azerbaijan Unit, UNESCO Chair in Bioethics recommends making written consent obligatory in the medical documents with signatures of the patients in them. The refusal to medical intervention with indication of possible consequences must be executed as a note in a medical document and is signed by a citizen or his legal representative and by medical worker.

Privacy/confidentiality. The physicians of Azerbaijan are obliged to keep a medical confidentiality under present legislation. Medical secret means information about application for medical aid, about health condition of a citizen, diagnosis and other information received during examination and treatment. Information on health condition cannot be given to a patient against his will. In case of unfavorable diagnosis, it should be said in a delicate way. A medical secret can be disclosed only by patient's consent. As exceptions are informing parents of an under-age person undergoing treatment, threat of spreading of infectious diseases, inquiries of law enforcement agencies and if there are reasons for doing harm to health.

Medical errors. This is one of the most important issues in medical law. In all the countries, the statistical data on this problem is available to the general public, which gives an opportunity to analyze the situation, reveal reasons and work on their removal. To our regret, such statistics is not done in Azerbaijan. Cases of initiation of legal action are very rare. Only high-profile cases that are made public come to court. Internal investigations results are never coming to the public. Due to International Medical Ethics Code a physician must be honest in his relations with patients and colleagues, he is obliged to fight against those of his colleagues who demonstrated incompetence or are noticed in deception. Standards of this Code still do not work in our country, as they should. Here we face other ethical standards that make one physicians cover up mistakes of the others. It follows from this that great attention should be paid to education and enlightenment in the field of bioethics and medical law of medical workers.

Medical errors may be divided into deontological, diagnostic and treatment. In the basis of deontological error lies breaking principles of due behavior of a physician in respect of a patient, i.e. non-observance of medical practice. The main reasons of diagnostical errors are disregard and incompetent use of anamnesis; not full examination of a patient, a mistaken interpretation of clinical findings, erroneous assessment of imaging logic and laboratory research, neglect and hurry in examination, false formulating of a diagnosis. Treatment errors are connected with mistaken clinical findings. As a consequence of such diagnoses, a patient is prescribed the

treatment not appropriate to the true nature of his disease, at the same time the necessary therapy is not held.

Harm to a patient or his death is not always connected with physician negligent of his duties. In such cases, respective actions or inaction of medical worker should be qualified as medical error. In the past medical errors were identified with intention. In modern law, an error is differed from an intention. As relations «physician – patient» are based on a contract, a physician gets fee in case of favorable outcome; but if harm is done to patient's health through physician's fault, the latter can be brought a suit against. In medical practice, there are three kinds of attitude to errors: denial, justification and removal ("medicine is powerless"). A medical error can be distinguished by subjective reasons: not enough qualification, incomplete information concerning diagnosis, belated examination, weak clinical thinking, self-confidence or lack of it.

Objective reasons bring together a medical error and an accident. The objective reasons are lack of information in medical science, delayed hospitalization, rareness of some diseases, a silent disease without any pronounced symptoms.

The main signs qualifying a medical error are observance of rules of professional conduct provided for by law, honest behavior while carrying out medical activity, objective nature of reasons entailing wrong action (inaction) of a medical worker.

A medical error without any signs of fault or crime is not punishable, but at all times medical community considered obligatory to examine and discuss these errors in order to avoid them in future.

To admit a physician's right to error does not seem possible, as the professional activity of a physician oriented to errors beforehand loses its humanistic nature. At the same time, causal relationship between actions (inaction) of a physician and worsening of patient's health or his death does not mean guilt of the physician.

Thereby, a medical error, from a legal point of view, must be qualified as a special case and should exempt a medical worker who committed it from civil and legal liability.

By opinion of national experts, the right to medical error may exist only if the harm is not connected with negligent carrying out their duties by workers of medical and pharmaceutical organizations. A specific order and procedures of considering citizens' complaints must be provided for in order to avoid a groundless accusation of a physician but careful assessment of the cases at the same time.

Medical insurance. Despite Law on Medical Insurance was adopted years ago in practice medical insurance system is not working largely. Only 2-3% of population is covered by regular medical insurance.

Ethic committees. Public health institutions don't have working ethic committees that may assess bioethical dilemmas, medical malpractice, hospital deaths cases.

B. Bioethical problems of transplantology. Technical aspects of transplantology do not cause difficulties, whereas legal, moral and psychological sides so far have remained problematic ones. The main problem of any transplantology is donorship. On the 28.12.1997 the law of Azerbaijan Republic "Human organ and (or) tissues transplantation" was adopted. Donation from corpses and alive people with preliminary consent is permitted. Donation with commercial purposes is forbidden: donating organs can't be subjects of trade. Azerbaijan practice shows that donation from alive people increasing but donation from corpses is not developing. Many experts suspect trade of organs behind official voluntarily donations from alive people. No postmortem donation cases had a place since 1997. This dangerous trend is result of undeveloped death investigation system and attitude to the corpses. However, some legal gaps also existing. According to Azerbaijan legislation organs and (or) tissues may be extracted from a corpse for transplantation if only there are indisputable proofs of death detected by expert physicians' council. Death resolution is based on statement of irreversible brain death,

which is not yet established by clear procedure, confirmed by the Ministry on Health of Azerbaijan.

As death investigation and transplantology & organ donation system is not well developed in the country despite existence of hundreds potential recipients the medical tourism with these purposes is getting larger.

Distribution of donated organs among recipients will be another bioethical problem where questions are more than answers at the moment.

Our mass media recently has reported about black transplantologists performing illegal operations on organ transplantation in some private hospitals of Azerbaijan. Surgeons were from Ukraine, donors were bringing from different countries. It has been a few months since an investigation has been launched. The results are still unknown but hospital was closed. However, the press considers these facts indicators of gaps in existing legislation and also of inactivity of the responsible structures. These structures must keep under control private hospitals, arrivals and activities of surgeons coming from abroad for the purpose of performing operation. It is a rude violation of the mentioned above law according to which buying and selling organs are prohibited. In Criminal Code of Azerbaijan Republic in article 137.1, is pointed out, that illegal buying and selling of human's organs and tissues is fined of five thousands of minimum wage, punished by reformatory works for a period of 2 years or by imprisonment for a period of 3 years along with deprivation of right to have a specific position or to a specific activity for a period of 3 years or without it.

International conventions also strictly condemn use of human organs as objects of commerce. In clause 8 of "Declaration of human organs transplantation" from 1987 is pronounced that buying and selling of human organs due to "Convention for the Protection of Human Rights and Dignity" is strictly condemned.

In clause 21 of the "Convention for the protection of rights and dignity of the Human Being" with regard to the application of biology and medicine adopted in Oviedo in 1997 is told that human body and its parts must not be a source of making financial profit.

Unfortunately, this problem becomes more and more urgent year after year in the world. It should be pointed out, that this topic ought to be considered in the intersection of 3 spheres – medicine, law and ethics. Azerbaijan joined international convention on forbiddance of buying and selling of human organs. In clause 17 of abovementioned law is specified that human organs cannot be objects of buying and selling.

In accordance with the law neither human organs and tissues, nor even cells cannot be removed (extracted or transplanted) against will of a human to whom they belong. But the law permits organ transplantation from corpse with donor's consent after his biological death, with his relatives' permission. It must be free of charge. And a transplantation must be realized in specialized medical institutions.

Thus, organ and tissue donors can be divided into 3 groups:

- A living human, genetically close to a recipient (near relation)
- A living human, not connected with ties of relationship, but acting voluntarily
- A human corpse

In developed countries the main stream of donor organs comes from human corpses that underwent brain death, that is those who after accidents, craniocerebral injury, tumours and other brain diseases remain in state of coma, they have no free breathing without mechanical ventilation of the lungs and there are no more perspectives of resuscitation. For example, in the USA it is forbidden to disconnect such people from mechanical ventilation without asking permission of relatives for use of organs as donor material.

Expansion of indications for different types of transplantology leads to "donor organs deficiency". It makes transplantologists to look for the "ways" to steady source of donor material. One of them results in necessity of detection "the moment of death", which, in the opinion of the experts, will considerably increase possibility of getting organs for transplantation. The other way becomes "early statement of brain death" and revelation of

“potential donors”. Both these ways determine a movement in the direction of pragmatic attitude to a human’s death. Nowadays brain death is legally recognized as equivalent to a human’s death in Civil Code of Azerbaijan. It is the only state in medicine, when physicians have all legal grounds to disconnect an apparatus for mechanical ventilation of the lungs right away after diagnosing. Naturally, such a high measure of responsibility requires absolute accuracy and definiteness from diagnostic criteria. But as mentioned above, “brain death” is not diagnosed nowadays in Azerbaijan due to absence of legally approved by Ministry of Health criteria.

We consider promotion of living donors is an alerting tendency in Azerbaijan. The mass media, without taking into account opinions of experts of medical law, for the sake of rating and sensations, invites famous people who underwent such operations, transplantologist and promote transplantology and alive donorship. Based on international recommendations Azerbaijan Unit, UNESCO Chair in Bioethics has recommended to stop promotion of alive donorship from television channels. In opinion of experts, not only in our country, but also all over the world, living donorship becomes a transaction, though legally it is executed as a free transfer of organs from a relative to a relative, but de-facto it is commercial deal and quite often transplantologists themselves take part in such bargains.

In our republic the system needs to be created that can regulate a large amount of legal and ethic questions in this field. For elaboration of such a system, the following will be important:

- truly functioning medical insurance system
- well-analyzed international experience
- reorganization of the whole system of death investigation in our country
- competent experts and managers.

For lack of this system, citizens in need of transplantation face numerous problems, one of which is an expensive operation. Thereby, only a man with good financial opportunities or having considerable support, like a businessman, an actor or an official can afford it. Then what are supposed to do for people, like a teacher, an engineer, a doctor or a pensioner? They cannot afford it, which breaks a principle of equal rights. So this brings to a conclusion that availability of medical aid for the citizens of our country differs: one category can afford it, the other has to die. This results in breaking international legal documents, to whom Azerbaijan joined, and in breaking national legislation.

Research into various methods of solution to this problem in other countries make it possible to search acceptable options for Azerbaijan for the purpose of guaranteeing the main rights of the citizens – right to live and to equal receipt of medical aid.

This step-by-step solution must be realized in accordance with the international legal regulations and with the national legislation that is in need of rapid development and improvement.

C. Bioethical problems related with death investigation

The second issue is that not all cases of deaths that must undergo forensic-medical and pathology investigation are investigated in practice. It makes many cases of hospital deaths not researched, death causes and medical errors undiscovered. Autopsy is obligatory by national legislation in cases of forensic-medical and pathologic anatomical needs (hospital deaths). Here, no need to stress forensic-medical reasons, but hospital death investigation must be stressed. Death in surgical and resuscitation departments after surgical intervention makes up the most of cases of hospital deaths. Widely-spread reasons for death in medical documents are pulmonary thromboembolism, coronary thrombosis, endointoxication. Bleeding of various aetiology, hypertensive crises may also be met. The most paradoxical is that these statements are based on nothing but hypothetical versions of doctor in charge, whose responsibility is investigated by internal commissions of the Ministry of Health. There are no acts of medicolegal investigations and no autopsies are done. Percentage of autopsies is 1-3% of the cases. This is simply explained: relatives did not allow, this contradicts traditions, Muslim customs, law permits that.

How much legal are such explanations? Due to clause 41 the “Pathologic anatomy autopsy» of the law of Azerbaijan Republic “On Protection of Population Health” (1997) signed by the president of Azerbaijan Republic Heydar Aliyev corpses of all person who died in medical institutions because of:

1. During pregnancy and childbirth.
2. Infectious diseases or if there is any suspicions of them
3. During or because of medical intervention.
4. If it is impossible to detect reason for death

are subjects to obligatory pathological anatomy autopsy irrespective of will of the relatives of the deceased. In all cases of death with the exception of abovementioned 4, an opinion of relatives may be taken into account. But in these 4 cases autopsy is compulsory, that is why documents going through investigation must be accompanied by autopsy, in most cases.

Not sending corpses to autopsy by hospital administrations is explained either by their lack of information, or of their carelessness and disinterest in the objective examination results of these cases. Everywhere is widespread to cancel an autopsy at request of relatives, most of all, for religious reasons. This cancellation is allowed easily and without hindrance, so one is under impression that heads of medical institutions feel sort of relief at this. In fact, reference to religious morals is no excuse because:

1. A compulsory autopsy is stipulated in our legislation in abovementioned cases.
2. An autopsy is permitted by Islam religion which dominates in Azerbaijan.

Why is an autopsy practiced in countries which are more religious by state structure, than Azerbaijan, which is a secular state? Islam considers this problem not easy, as it is connected with causing damage to physical integrity of human body, the creation of the Almighty that demands respectful treatment. Nevertheless, an autopsy is believed to be legal if is performed in the interests of science or for the sake of finding out the truth in investigation. In Muslim countries (Iran, Saudi Arabia, Pakistan, UAE) it is impossible to disregard posthumous examination of a corpse, if the cause of death is not known.

D. Bioethical problems related with genetically modified food products turnover

Azerbaijan is one of few European countries where national legislation does not reflect its attitude to free uncontrolled turnover of genetically modified food products on its own territory. Taking into account alarms of scientists in terms of safety for human health, ecology and environment and strengthening legislation developments in European and CIS countries towards such products we need to act accordingly. Otherwise, this situation deteriorates the rights of citizens for information, usage of safe food products, life in healthy and safe environment as well as economical safety of the state.

In conclusion, we wish to stress our wish that development of bioethics in Azerbaijan, arming different professionals by bioethical and medico-legal knowledge, increase of public awareness to bioethical dilemmas and issues and human rights will help to become real democratic country when ethical challenges are solved in the best way for people on the bases of equality, justice and equity.

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Main bioethical challenges in Azerbaijan that should be responded by medico-legal specialists

Key bioethical challenges, which are typical for Azerbaijan and which in the author’s opinion are to be responded in the near future are elucidated in the article. In particular the author highlights the issues of Patients rights and bioethical problems of public health, medical errors, bioethical problems of transplantology, problems related with death investigation etc. Finally the author gives a brief analysis of the current issues connected with genetically modified food products in Azerbaijan.

Key words: bioethical challenges, informed consent, medical intervention, transplantology, genetically modified food products.