of the European Union. Other occasions were related to stories with ethical controversies published in the media, e. g. on human cloning, creation of human embryos for research. embryonic stem cells, gene technology, and end of life decisions, including euthanasia.

In ethics of biomedical research, Slovenia has had a long tradition. Nevertheless, the protocol on biomedical research was useful for the work of the Research Ethics Committee at sensitive points, such as dependent position of persons invited to participate, the conditions for the use of placebo, conflict of interest of the researchers, information to be supplied and evaluated etc. A national legal instrument based on the Protocol has so far not been elaborated, but its provisions already apply.

These issues remain open, in particular medical care of the terminally ill and the dying. So, regarding the future work in bioethics by the CDBI, Slovenia would support a project of *re-examining some end-of life issues*.

Council of Europe had addressed human rights related to end of life situations before, for example by producing a Recommendation of the Parliamentary Assembly on the rights of the terminally ill and the dying (Rec 1418 of 1999), and a more recent Recommendation on palliative care (Rec (2003) 24 of the Committee of Ministers). Nevertheless, the issues of human rights near the end of life remain a pressing and partly controversial topic. A recent questionnaire on the relevance and added-value of the Council of Europe's activities in the field of bioethics has shown that most delegations to the CDBI selected precisely that topic as a preferred activity in the CDBI's future work. For this reason, at its 34th Plenary Meeting of June 3-5 2008, the CDBI has decided to resume the debate on this topic in the form of a seminar planned for 2010 (*Seminar on decisions in relation to medical treatment at the end of life*).

The Slovenian delegation would like to propose that the debate focuses on the question of terminal versus palliative sedation. Deep sedation is increasingly used as a valuable medical treatment providing full relief even in cases of extreme suffering due to intractable pain and distress. On the other hand, there is a serious concern that it could be misused as a kind of euthanasia. A guideline or recommendation proposing safeguards would be very useful.

There is also an initiative to elaborate an Additional Protocol on the protection of human rights and dignity of terminally ill and the dying, to the Oviedo Convention. The Protocol could be based on the already mentioned Recommendation 1418 of the Parliamentary Assembly. Slovenia is in favour of the initiative and would like to propose that feasibility of such a project is carefully examined.

Among other possible projects the Slovenian delegation would support an instrument, at least a recommendation, but preferably a Protocol, on the protection of embryo in vitro, a Protocol concerning the protection of human rights and dignity of persons with mental disorder, and Guidelines concerning access to medical files.

In conclusion, medical doctors, biomedical scientists and ethicists in Slovenia appreciate the Oviedo Convention with its protocols and other bioethical projects of the Council of Europe as an exceptionally important milestone in the development of ethical standards in our country.

Reference

[1] Trontelj, J.: *Impact of Oviedo Convention and its Protocols on Legislation and Practices in Slovenia*. Council of Europe Regional International Bioethics Conference: Oviedo Convention in Central and Eastern European Countries. Bratislava, 24-25 September 2009.

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IMPACT OF THE OVIEDO CONVENTION AND ITS PROTOCOLS ON LEGISLATION AND PRACTICES IN GEORGIA

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1. Introduction, General Framework of Georgian Legislation on Human Rights and Biomedicine

The process of the development of health, biomedicine and human rights legislation in Georgia was greatly exposed to the influence of extensive movement for health care reform in Europe (research, educational and legislative activities related to human rights in health and biomedicine) on the national as well as international/regional levels. Reform of Legislation of Georgia in this sphere started in 1990s (1995-97), before Georgia became the member of the Council of Europe in 1999.

Principles and provisions of various binding as well as soft legal instruments in the field of health and human rights have been incorporated to national law. So, the legislation of Georgia on human rights and biomedicine has been significantly influenced by strategies and principles presented in various international developments. The documents playing most important role in pushing and promoting the process of drafting the health and human rights legislation in Georgia were Convention on Human Rights and Biomedicine and its additional protocols (the Council of Europe) and "Declaration on the Promotion of Patients' Rights in Europe" (WHO).

Legislation of Georgia in the field of Health and Human Rights comprises the Constitution of Georgia, International agreements and treaties to which Georgia is a party (including Oviedo Convention and its protocols; *see below*), National Laws and other legislative and regulatory texts.

Currently National Laws of Georgia related to human rights in health care and biomedicine cover almost all aspects of the problem and includes the following documents, as given in the **table 1** (p. 17).

From these laws the "Law of Georgia on Health Care" is

considered to be the general, framework law, which concerns all aspects of health and biomedicine, determines the priorities and sets out fundamental principles of the health care legislation of Georgia.

Table 1 Georgia National Laws Related to Human Rights in Health Care and Biomedicine

	ADOPTED	LAST UPDATE
The Law on Health Care	1997 (10.12)	2008 (21.03)
The Law on the Rights of Patient	2000 (05.05)	2007 (08.05)
The Law on Doctor's Professional Activity	2001 (08.06)	2008 (21.03)
The Law on Public Health	2007 (27.06)	no updates
The law on HIV/AIDS Prevention	1995 (21.03)	2000 (08.11)
The Law on Psychiatric Care	2006 (14.07)*	2008 (01.11)
The Law on Blood Donors and Blood Components	1997 (30.04)	2006 (29.12)
The Law on Human Organ Transplantation	2000 (23.02)	2006 (23.06)
The Law on Drug and Pharmaceutical Activity	1996 (25.12)	2008 (18.06)
The Law on Narcotic Drugs, Psychotropic Substances, their Precursors and Narcologic Care	2002 (05.12)	2007 (08.05)
The Law on Protection and Promotion of Infant Natural Feeding	1999 (09.09)	2000 (09.06)
The Law on Medical and Social Expertise	2001 (07.12)	2007 (16.03)
The Law on Tobacco Control in Georgia	2003 (06.06)	–
The Law on Biomedical Research Involving Human Subjects	Before Parliament	
The Law on Reproductive Health and Reproductive Rights	Before Government	

* This Law replaced the previous Law on Psychiatric Care adopted in 1995 (21.03)

The "Law on the Rights of Patients" is specific law defining all major principles of human rights protection in the field of health care.

The "Law on Doctor's Professional Activity" defines responsibilities of doctors before patients as well as regulates all major aspects of doctors' training, professional development and activity.

The "Law on Public Health" has relation to human rights as far as it defines rules of interrelation between citizens and public health system and in a few, very specific, cases restricts rights of individuals for the sake of public interest.

Other laws regulate human rights issues in the context of various specific fields of medicine, such as psychiatry, human organ transplantation, HIV/Aids etc.

2. Ratification of the Council of Europe Instruments on Human Rights and Biomedicine

Georgia has signed and ratified the ***Convention on Human Rights and Biomedicine*** and its two Protocols – ***Protocol on the Prohibition of Cloning Human Beings and Protocol concerning Transplantation of Organs and Tissues of Human Origin.***

The ***Protocol concerning Biomedical Research*** was signed on 21 February, 2005, but still is not ratified by the Parliament. The data about signing and ratification of the instruments related to human rights and biomedicine of the Council of Europe are given in the **table 2**.

Currently the Parliament of Georgia in cooperation with the Ministry of Foreign Affairs and the President's office is working on ratification of ***Protocol concerning Biomedical Research.*** It is expected that the document will be ratified before end of 2009.

Simultaneously the ***draft Law on Biomedical Research Involving Human Subjects*** will be discussed at the Parliament as the instrument for implementation of the above protocol on biomedical research (*details on the development of the draft law are given below*).

3. Impact of the Oviedo Convention on Georgian Legislation

The impact of the Council of Europe instruments in the field of human rights and biomedicine, particularly the Convention on Human Rights and Biomedicine and its additional protocols on current legislation of Georgia are substantial. Even before Georgia joined the Council of Europe and the Oviedo Convention was ratified, considerable part of Georgian legislation on health, biomedicine and human rights was already harmonized with main provisions of the Convention.

Convention on Human Rights and Biomedicine

Almost all conceptual statements of the Oviedo Convention are included in the laws being prepared after 1997 – "Law on Health Care", "Law on the Rights of Patients Rights", "Law on Human Organ Transplantation", draft "Law on Biomedical Research Involving Human Subject",

Table 2 Signature and Ratification of the Oviedo Convention and its Additional Protocols by Georgia

Convention and its Protocols	Date of Signature	Date of Ratification	Date of the deposit	Entry into force
Convention on Human Rights and Biomedicine	11.05.2000	27.09.2000	22.11.2000	01.03.2001
Protocol on the Prohibition of Cloning Human Beings	11.05.2000	27.09.2000	22.11.2000	01.03.2001
Protocol concerning Transplantation of Organs and Tissues of Human Origin	25.03.2002	27.09.2002	18.12.2002	01.05.2006
Protocol concerning Biomedical Research	21.02.2005	20.10.2009	–	–
Protocol concerning Genetic Testing for Health Purposes	–	–	–	–

"Law on Doctor's Professional Activity" etc. The drafting process of the above laws took place before the Convention was signed and ratified.

Taking into consideration the above-mentioned reality, that the national legislation has been already harmonized with the Convention, the ratification of the Convention by the Parliament of Georgia went smoothly. Finally the Convention on Human Rights and Biomedicine and the Protocol on the Prohibition of Cloning Human Being were ratified by the Parliament of Georgia without making any reservation.

Protocol on the Prohibition of Cloning Human Beings

Actually the Law on Health Care (adopted in December 10, 1997) was influenced by the Protocol on the Prohibition of Cloning of Human Beings even before the Protocol was opened for signature (January 12, 1998). Georgian Law prohibits human cloning based on the article 142 of the Law on Health Care. This article was influenced by the debates within the Council of Europe around the draft protocol in 1997. So, Georgia is, probably, the first country which prohibited human cloning by law, although the text of the relevant article is not close enough to the language of the protocol (*see below*): "*Human cloning by use of the methods of genetic engineering is prohibited." (Law on Health Care, Article 142.1).*

The anti-cloning protocol itself entered into force in Georgia in 01.03.2001, like 4 other countries, which ratified it earlier. Georgia was the 5th country, which ratified the Protocol on the Prohibition of Cloning of Human Beings.

Protocol concerning Transplantation of Organs and Tissues of Human Origin

Georgian Law on Human Organ Transplantation was adopted in 2000. i.e. before the protocol was opened for signature (January 24, 2002). However, Georgian Law was influenced by Convention itself (Chapter VI of the Convention and other relevant articles). Georgian legislation on human organ transplantation incorporates all precautionary provision of the Convention aiming at protecting life, health and dignity of organ donors and recipients, particularly vulnerable groups and minimizing the possibility of organ trafficking.

The law establishes so-called "opt-in" system for organ removal from dead donors, which is thought to be better system for Georgia, taking into consideration the country context – attitude of the society, lack of resources and experience. Convention does not specify which system is preferable; however, it outlines general principles and approaches, which are taken into consideration in Georgian law.

According to Georgian legislation the circle of the living donors is restricted to genetic relatives and spouse of the recipient. Later, in November 2002 amendment was made to the Law on Human Organ Transplantation, which partly widened the circle of living donors and so-called "cross donorship" or "donor exchange" was allowed (organs could be swapped between two pare of donor-recipient if tissues are not compatible within pairs). However, while making this amendment, restrictions articulated in the Protocol concerning Transplantation of Organs and Tissues of Human Origin were taken into consideration (particularly, Article 10 – Potential organ donors). The letter states that donor shall have "a close personal relationship" with recipient (as defined by law) or if such relationship does not exist, organ removal can take place "only under the conditions defined by law and with the approval of an appropriate independent body".

Protocol concerning Biomedical Research

As mentioned already Georgia is being prepared to ratify the protocol on research. This process includes discussion and adoption of the Law on Biomedical Research on Human Beings.

The first version of the draft law was prepared in 1999-2000. Later, it was submitted to the Council of Europe for comments. The draft law has been reviewed by the expert appointed by the Council of Europe and updated in 2001 according to the comments provided. However, its adoption was delayed at the Parliament. This gave an opportunity to review it in 2006-2007 again in the light of the Additional Protocol concerning Biomedical Research (the draft Law has been discussed during the DEBRA meeting in Tbilisi in 2006).

The current version of the draft law is in line with the protocol and the Parliament plans to discuss it and start its adoption simultaneously with the Protocol concerning Biomedical Research.

Currently biomedical research on human beings in Georgia is regulated by the following three instruments:

- CoE Convention on Human Rights and Biomedicine (Signed by Georgia in May 2000; Ratified by the Parliament in September 2002; Entered into force on 1 March, 2001);
- Law of Georgia on Health Care (Adopted by the Parliament of Georgia in December, 1997);
- Law of Georgia on Drug and Pharmaceutical Activity (Adopted by the Parliament of Georgia in 1995; Updated in 2001).

The law on Health Care includes separate chapter – Chapter XIX "Biomedical Research", in which basic principles regulating biomedical research are set out. Particularly according to the above-mentioned law:

- aims, objectives, methods and possible outcomes of the research should be specified in the research protocol; research should be carried out only within the frames of the research protocol;
- research protocol should be reviewed by independent body and ethics committee;
- risks and benefits of the research should be assessed; risk associated with the research should not be disproportional to the expected benefits;
- research subject should be fully informed about the details of the research (objectives, methods, potential benefits, risks, alternatives etc.);
- research should not be started without informed consent of the research subject;
- research subject has the right to refuse to participate in the research or withdraw from the research at any time despite already given written informed consent.

The law also outlines general principles for the protection of incapable persons and minorities in the context of biomedical research.

Although, it was important step forward when the above provisions were incorporated in the Law on Health Care, it lacks specificity and does not cover various aspects of biomedical research. Also, it does not give clear guidance about the role and function of research ethics committees.

The law on Drug and Pharmaceutical Activity (just one article) sets out general rules for protecting human subjects during clinical trials. It requires ethics committee to be created at the institution where the trial is planned to be carried out. The committee is created for each trial during the whole process of research.

The Law on Drug and Pharmaceutical Activity prohibits research on imprisoned individuals and military servicemen. This could be regarded as form of discrimination. Also, such approach prevents to carry out specific research projects which are relevant only to prison environment.

Interestingly, this law specifically mentions recommendations set out in WMA Declaration of Helsinki as the basis for conducting clinical trials on human beings. This also creates problem, because there are various versions of the Declaration and the provisions vary significantly from version to version.

The new draft Law and the additional Protocol concerning Biomedical Research are expected to fill this gap and establish effective framework for carrying out biomedical research on human beings according to current ethical and legal standards. This will be particularly helpful for research ethics committees.

Protocol Concerning Genetic Testing for Health Purposes

There were no new developments in this sphere since the protocol was opened for signatures. However, in the Law on the Rights of Patients (adopted in 2000) there is specific chapter "Rights in the Filed of Genetic Counselling and Gene Therapy", which has been influenced by the Convention. Also, the Law on Health Care includes provisions on genetics.

The above legislation covers the issues related to genetics and healthcare in general terms. Particularly it concerns the following issues:

- non-discrimination;
- general conditions to perform gene therapy;
- general conditions to perform genetic testing;
- restrictions for the interventions seeking to modify the human genome;
- prohibition of sex selection.

4. Impact of the Oviedo Convention and its Additional Protocols on Practices

Although there are no official and well structured studies on the impact of Oviedo Convention and its protocols on practices in Georgia, certain influence on activities of specific bodies/structures could be observed. Some examples on such influence are given below.

The National Council of Bioethics regularly refers to the Oviedo Convention and its Protocols in the process of making decisions and recommendations on specific issues. Such recommendations are related to human organ transplantation, stem cells, end of life, palliative care and euthanasia, psychiatry etc.

Georgian Government based on the recommendation of the National Council on Bioethics made its decision during international debates on UN level concerning prohibition of human cloning (developing the text of the United Nations Declaration on Human Cloning). This decision was based on the fact that Georgia has ratified Oviedo Convention and its Additional Protocol on the Prohibition of Cloning Human Beings. On the other hand the Law of Georgia on Health Care specifically prohibits human cloning.

The Oviedo Convention is used in the process of education/training of health care professionals and lawyers. Recently detailed comments to the Convention have been developed for lawyers in Georgian language and the Georgian text of the Convention has been disseminated among Georgian doctors (3000 copies).

Association of Transplantologists of Georgia considers the Convention and additional Protocol concerning Transplantation of Organs and Tissues of Human Origin in decision-making process.

Additional Protocol concerning Biomedical Research as well as Oviedo Convention are intensively used in the process of ethical review of research projects, which involve human beings. This is done by:

- National Council on Bioethics (usually does not review specific research projects, unless specifically requested; particularly when projects are multicenter and/or international and/or entailing high risk);
- Local research ethics committees.

Some specific provisions of the Convention have been reflected in the Code of Ethics of Georgian Physicians, which has been developed and endorsed in 2003.

However, the Oviedo Convention and its additional Protocols are not widely known, referred and/or followed by relevant professionals – health care providers, lawyers, policy makers and even the members of research ethics committees. More efforts are needed for their popularization. Such efforts should include development and implementation of specific modules to teach the above instruments of the Council Europe on undergraduate as well as postgraduate level for health care professionals and lawyers. We expect that the "A Guide for Research Ethics Committee Members", which is currently being prepared within the CDBI, will be particularly helpful for research ethics committee members and researchers in applying to practice the provisions of the Convention and its protocol on biomedical research. Having such practical guidance for other spheres as well, which are covered by Convention and its protocols, could considerably improve implementation of the above instruments of the Council of Europe.

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Prof. Givi Javashvili, MD, PhD. – his background in the field of bioethics and health and human rights spans about 15 years. He worked as an expert-consultant at the Department of Health Law and Bioethics of the National Health Management Centre since its establishment (1995). He is drafting group member for laws on health care, patients' rights, doctor's professional activity, organ transplantation etc. He is nominated national expert to the Council of Europe Steering Committee on Bioethics (CDBI) since 1999, Bureau member of CDBI in 2002-2006. Currently, he is Working Group member, which is in charge of drafting international guidelines for Re-search Ethics Committees. He is also involved in many teaching/training activities in the field of bioethics at the undergraduate and postgraduate levels. He is author of various articles, publications and education materials on health, ethics and human rights.

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