Medicínska etika & Bioetika – Medical Ethics & Bioethics
Volume 16, 2009, Supplementum 1, pages 1 – 32

ISSN 1335-0560

Printing of this publication has been supported by DG III Social Cohesion, Council of Europe, Strasbourg within the Program DEBRA. The information, opinions, and positions contained in this volume are those of the authors and may not necessarily reflect the positions of the Council of Europe on the same issues.

Printed copies may be ordered from the Institute of Medical Ethics and Bioethics n. f., Vysoká 32, 811 06 Bratislava, Slovak Republic, or downloaded from the Institute's web page at http:\\www.bioethics.sk.

Printed in the Slovak Republic

Oviedo Convention in Central and Eastern European Countries

Proceedings of the Council of Europe Regional Conference „Oviedo Convention in Central and Eastern European Countries" September 24 – 25, 2009, Bratislava, Slovak Republic

CONTENTS

FOREWORD

The 10th anniversary of entering into force of the Convention on Human Rights and Biomedicine (Oviedo; 1997) that is remembered in 2009 offers an opportune moment for a deeper reflection on the impact the Convention and its Additional Protocols have had on the human rights and biomedical legislation and on good practices in Europe (and beyond) – and also on the possible ways forward with regard to its/their ratification/s and implementation.

In promoting and supporting such reflection with regard to and within the countries of Central and Eastern Europe, the Secretariat of the Steering Committee on Bioethics (CDBI) of the Council of Europe, in collaboration with the Slovak Ministry of Health, Slovak Medical Association and the Institute of Medical Ethics and Bioethics n. f. in Bratislava, organised *The International Bioethics Conference – "Oviedo Convention in Central and Eastern European Countries"*, the regional conference under the program DEBRA, which took place on September 24 – 25, 2009, in Bratislava (details at www. bioethics.sk).

This volume of proceedings contains edited manuscripts of the addresses, papers and country reports presented at the meeting, supplemented with a brief overview of the most important issues tackled and conclusions reached during those two interesting and intensive working days in Bratislava. They were marked by constructive discussion, sharing of experience and factual information, as well as by the kind personal contributions of all participants towards the unique atmosphere of mutual understanding, respect and friendship.

The editor is greatly indebted to the authors of papers contained in this volume for the collegial understanding and collaboration, especially for providing their manuscripts, with all required changes and additions, in the shortest possible time span and with a 'friendly hug'. We hope the readers find the information and ideas provided interesting and useful.

October 27, 2009

Dr. Jozef Glasa
Director, IMEB n. f.

HONORARY ADDRESSES

ADDRESS OF MR. RICHARD RAŠI, MINISTER OF HEALTH OF THE SLOVAK REPUBLIC

Mr. Chairman, Ladies and Gentlemen,

let me cordially greet and welcome you in the capital of the Slovak Republic. I am glad that our country has become a place for such a significant meeting and I have no doubt that the conference will bring many inspiring ideas.

The bioethics issue increasingly resonates and with its impact belongs to the current challenges which have to be handled. However, just at this meeting you will discuss the International Convention on Human Rights and Biomedicine and in the conclusions of the conference will certainly dominate the value of contribution of International Convention and its Additional Protocols, their application in practice of the Council of Europe member countries in Central and Eastern European region. The importance of the Bratislava' conference is also in that, that its results will be presented at the European Conference of the Council of Europe in Strasbourg in November, and it will be one of the major activities on the occasion of 60th anniversary of the Council of Europe.

Let me at this forum point out that the Slovak Republic was among the first signatory and ratifying countries of the International Convention on Human Rights and Biomedicine and number of its protocols. Today we can state that the text of the Convention is applied in the formulation and amendment of legislation in our respective fields and the Slovak Republic was the beneficiary of know-how in several international conferences and seminars organized by the Council of Europe in Bratislava with the support of DEBRA program.

Currently, the activities of the Steering Committee for Bioethics focus on technical assistance to particular countries, especially in Central, Eastern or Southeastern Europe in the implementation of effective legislative texts in practice, and Slovakia is already a country, which in regard of the reached development stage and EU membership can not be any longer a direct receiver of the support in the scope of DEBRA program. Now Slovakia itself may participate on these major activities of the Council of Europe.

Resolving of the ethical dilemmas and their application in practical solutions to everyday biomedicine often requires appropriate legislative action, which is wider professional and political debate. There is the Ethical Committee working by the Ministry of Health, and we consider its position as an extremely important and its mission as irreplaceable.

Health is everyone's most personal ownership and the center of society-wide interest, even beyond the frontiers. In the context of biomedicine and bioethics issues for all of us is the subject of intense reflection accompanied by a sense of responsibility for further development. Our unity in this direction will be important and Slovakia is ready to support it. Because health is the same value from the point of view of the Slovakia, European Union or the global world and we all know very well that its price can not be financially quantified.

Ladies and gentlemen, let me express my thanks for organizing this meeting, which I see as a serious search for answers to important societal challenges. It is also a suitable platform that contributes to the European harmonization of views on ethical issues. Allow me to wish you a successful negotiation process and inventive atmosphere. I believe that the conference will establish an opportunity to make new contacts and the creative discussions.

ADDRESS OF MS. AYŞEGÜL ELVERIŞ COUNCIL OF EUROPE

Minister, Deputy Ministers,
Members of the Honorary Presidium,
Dear Participants,

As the representative of the Council of Europe, it is an honour and a great pleasure to welcome you to this International Bioethics Conference on Oviedo Convention in Central and Eastern European Countries.

First of all, I would like to express my gratitude to Mr. Richard Raši, the Minister of Health of Slovak Republic who appreciated the importance of this event and who kindly provided this excellent Congress Centre for us to hold the Conference.

I would also like to associate to my thanks the Slovak Medical Association as well as the Institute of Medical Ethics and Bioethics, and in particular Prof. Jozef Glasa, for their very efficient collaboration on the organization of the Conference.

In the history of Bioethics, the Oviedo Convention represents a remarkable accomplishment since it is the first and – as to date - the only legally binding instrument elaborated in this field. But this is certainly not its only asset. The Convention is also the first international instrument placing Human Rights right into the heart of discussions around the application of biology and medicine. This probably explains why it became over the years a reference not only at the national level but also at the international level. I also believe that the Convention's impact on domestic laws and practices of States that have ratified it, as well as those that have not ratified it, proves its significance.

In that connection, I would like to recall that next month we will be celebrating the 10th anniversary of the entry into force of the Convention. To hold this conference in Bratislava is almost symbolic in that sense, since **Slovakia was the first country to ratify the Convention** (15 January 1998), in other words, the first country to contribute to its entry in force. Likewise Slovakia was also the first country to ratify the additional Protocol on the prohibition of cloning human beings as well as the additional Protocol on biomedical research.

This conference is organized by the Council of Europe within the framework of its cooperation activities. These cooperation activities aim to inform about the principles laid down by the Council of Europe legal instruments as well as to identify and understand the difficulties encountered by national authorities when they implement these principles. This "close-up" approach facilitates the implementation of relevant principles and contributes to the development of harmonized legislation and practices in the Member States.

That brings me to the topic of this Conference. For the next two days, we will be focusing on the impact of the Convention in your respective countries, on the difficulties encountered by the countries that have not yet ratified the Convention, and on the future challenges that

it's facing. This will give us an overview of the situation in central and Eastern Europe. For this reason, I am looking forward to the presentations of the speakers and the country representatives.

I am also confident that the discussions which will take place during the different round tables will be extremely rewarding and the final report of this Conference, which will be presented by Prof. Glasa on the occasion of the 10th anniversary of the entry into force of the Convention will be of great relevance.

Before I hand over to Mr. Fronczak, the Deputy Minister of Health of Poland, I wish you all a very fruitful conference and want to say once more on behalf of the Council of Europe: "Vďaka našim hostiteľom a vitajte!"

ADRRESS OF MR. ADAM FRONCZAK, SECRETARY OF STATE, MINISTRY OF HEALTH, POLAND

Dear Minister,
Ladies and Gentlemen,

I would like to congratulate sincerely the initiators and hosts of this conference, the Secretary General of the Council of Europe, the Slovak Medical Association and the Institute of Medical Ethics and Bioethics on their efforts put into organising this event.

I would also like to thank Minister Raši for taking this event under the auspices of the Ministry of Health of the Republic of Slovakia. I would also like to express my gratitude to the organisers for inviting me to join in the discussions in such an outstanding professional circle.

The topics of this meeting are important and difficult, as are the matters regulated by the Oviedo Convention. Today, we have a unique opportunity to jointly discuss the most important problems and dilemmas that the countries of our region are facing as a result of the ever increasing pace of the medical technology development. Though often stimulated by lofty ideas of science or simply by free market mechanisms, this development, very often, loses sight of the most important issue: that any advancement of science or technology should primarily serve the people. This is why we cannot ignore the ethical, legal, and social implications of the use of the latest medical developments.

These problems and dilemmas are so significant that many member States of the Council of Europe have not signed or ratified the Convention so far. This meeting provides a great opportunity for us to share our experiences of both legal and practical solutions to these issues, as well as to discuss the problems that many countries are still facing.

Ladies and Gentlemen, I hope that we are going to have an interesting and fruitful discussion, which will help to accelerate the adjustment process of national legislation to the standards set up by the Oviedo Convention.

INVITED PAPERS

OVIEDO CONVENTION AND ITS PROTOCOLS – ETHICAL AND LEGAL REFLECTION ON BIOMEDICINE IN EUROPE

Ayşegül Elveriş

Bioethics Division, Health and Bioethics Department, Directorate General of Social Cohesion, Council of Europe, Strasbourg

The Convention on Human Rights and Biomedicine is the first international instrument that addresses the **linkage** between human rights and biomedicine. The motivation behind the Convention was in fact provided by the spectacular progress achieved in biology and medicine. Without any doubt, this progress was - and still is - the source of great achievements in matters of health. However, it also raised and continues to raise concerns about the respect of fundamental values concerning human rights and human dignity.

Aware of these potentially negative aspects of the progress in the field of biomedicine, the then Secretary General of the Council of Europe, Mrs Catherine Lalumière, proposed in June 1990 the elaboration of a Convention on Bioethics on the occasion of the 17th Conference of the European Ministers of Justice. Following the approval of this proposal, the Committee of Ministers instructed the Ad hoc Committee of Experts on Bioethics (which later has been replaced by the Steering Committee on Bioethics - CDBI) to prepare "*a **framework convention setting out common general standards for the protection of the human person in the context of the biomedical sciences***". The Convention was to be complemented by Protocols on specific aspects. In July 1994, the first draft of the Convention was opened for public consultation. The CDBI presented the final draft in June 1996. After approval by the Parliamentary Assembly, the Convention was finally adopted by the Committee of Ministers on 19 November 1996 and opened for signature in Oviedo, Spain, on 4 April 1997. To date, it has been signed by 34 countries and ratified by 23 of them.

In structural terms, the Convention is a **framework instrument**: i.e. it limits itself to setting out the fundamental principles for the protection of human rights and human dignity in the areas concerning the application of biology and medicine, and leaves detailed rules on specific aspects for Additional Protocols.

Before I elaborate on the provisions of the Convention in more detail, I would like to recall the universally recognised principles of medical ethics: **autonomy, confidentiality, beneficence/non-maleficence and justice**. These principles are all based on the broader notion of **human dignity** and they are all addressed in the Convention in several provisions.

In that context, the first point to underline is the force with which the Convention defends human dignity. Right from the opening articles the Convention points out that its aim is to **protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine**. As the direct corollary of the idea of human dignity, Article 2 points out that the interest and welfare of the human being shall prevail over the sole interest of society or science. The importance atta-

ched to human dignity is also reflected in Article 11, which prohibits discrimination based on genetic heritage. This article extends the prohibition of discrimination contained in Article 14 of the European Convention on Human Rights (ECHR), adding a new prohibition on discrimination on the ground of genetic heritage.

The principle of **justice** find its translation in Article 3 of the Convention. Article 3 address the issue of equal access to healthcare; in that connection it should be underlined that this article is not formulated as an individual right but in the form of a best efforts obligation imposed on States. The principle of **beneficence and non-maleficence** is the basis for Article 4 which addresses the obligation for health professionals to act according to professional standards.

As to the **autonomy** and **confidentiality principles**, they find their concrete applications in Chapters II and III of the Convention devoted to the issue of consent and the respect of privacy respectively.

- The issue of **consent** has a significant place in the Convention. Articles 5 to 9 establish the well-known rule of biomedical ethics, according to which medical treatment may only be carried out after a patient has been informed of the purpose, nature, risks and consequences of the intervention, and has freely consented to it. There are two exceptions to the right to decide for oneself. Firstly Article 7 stipulates that, subject to protective conditions prescribed by law, a mental patient may be treated without his or her consent where non-performance would seriously endanger his or her health. Secondly, in emergency situations (e.g. where a patient is in coma after an accident) the doctor may adopt all treatment measures needed for the good of the patient, even without his consent (Article 8).
- Article 10 § 1 deals with the **right to privacy** regarding health information and constitutes the translation of the ethical principle of confidentiality into legal language and a specific application of the more general right to privacy set out in Article 8 of the ECHR. According to Article 10 § 2 two other rights derive from the right to privacy: the right to be informed (right to know) and the right not to be informed (right not to know) about one's health condition. The right to be informed about one's health status is a natural consequence of the full recognition of the patient as a person, i.e. as an autonomous being. Similarly the right not to be informed is likewise an expression of autonomy, of the legitimate desire of a person not to receive potentially harmful information about his or her health status, especially when there are no treatment or preventive measures available.

The following chapters of the Convention identify a number of principles applicable to the new biomedical techniques.

- Chapter IV addresses the issue of human genome:

Article 12 allows for genetic testing to predict genetic diseases only if the tests are conducted **for health purposes** or as a part of a related scientific programme. In both cases, the person concerned must give his or her consent and must be offered **appropriate genetic counsellin**g. In accordance with **Article 13**, interventions to modify the human genome can only be undertaken if two conditions are met: firstly, they must be conducted **for preventive, diagnostic or therapeutic purposes**. Secondly, **no modification may be introduced that may affect offspring**. Chapter IV on the human genome closes with a **prohibition on the use of assisted fertilisation techniques to choose the sex of the future child**, the sole exception being the avoidance of serious sex-related heredity diseases.

- Chapter V lays down general rules on biomedical research:

The principle of freedom of research is expressed in Article 15. **Article 16** determines the conditions for research on human beings: research subjects should give their **free, explicit and informed consent; no alternative** comparable effect may exist (for example animal research), and the risk for the research subject should not be **disproportionate** to the potential benefit of the research. Moreover, the research project should be approved by an independent body which shall assess its scientific merits and its ethical acceptability. **Article 18** provides that, in case research on embryos *in vitro* is allowed by law, adequate protection of the embryo must be guaranteed; the creation of human embryos for research purposes is prohibited.

- Chapter VI sets up the conditions for organ and tissue donation by living donors for the purpose of transplantation:

Accordingly, the removal of organs or tissue from a living person for the purpose of transplantation may only be carried out for the **therapeutic benefit of the recipient** and where there is **no suitable organ or tissue available from a deceased person** and **no alternative therapeutic method of comparable effectiveness**. Specific and express consent in written form or before an official body is necessary prior to any intervention in that context.

For both biomedical research and organs transplantation, specific attention is addressed to protection of persons not able to consent (Articles 17 and 20).

As already mentioned, the Oviedo Convention is a framework convention. It contains general principles, which are intended to be developed by means of additional protocols, each dealing with a separate sphere of biomedical field. To date, four additional protocols have been opened for signature: One concerning the prohibition of the cloning of human beings (1998), one on the transplantation of organs and tissues of human origin (2002), one on biomedical research (2005) and one on genetic testing for health purposes (2008). The Convention and its Additional Protocols form their own convention system, meaning that a state may only sign or ratify a Protocol, if it has already signed or ratified the Convention.

Additional Protocol on the Prohibition of Cloning Human Beings

(Entry into force 1 March 2001)

The issue of human cloning was not considered when the Oviedo Convention was elaborated. In fact, the final version of the Convention was adopted in November 1996, a few months before the announcement of the birth of Dolly, the first cloned mammal. This is why the Council of Europe decided in 1998 to address the issue through an additional protocol specifically devoted to this topic. The Protocol prohibits any intervention having the aim of creating a human being genetically identical to another human being, whether alive or dead, irrespective of the technique used.

Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin

(Entry into force 1 May 2006)

The protocol was opened for signature in January 2002. It stresses that the removal and transplantation of organs must take place in a well-structured system facilitating equitable access by patients to transplantation, in accor-

dance with clearly defined qualitative and ethical standards. The Protocol explains that no organs may be removed from the dead body of a person who would have opposed such removal while alive. Since organ donation must remain a literal donation, both for moral reasons and in order to prevent any sale or traffic, there is an absolute ban on profits or payments linked to the organ itself, with the obvious exception of the expenses arising out of the medical and technical acts performed in connection with the transplantation.

The protocol also tackles the problem of removing organs and tissues from living persons. In that case, organ removal can only be authorised for therapeutic purposes, and on the condition that the donor has close personal relations with the recipient, but also under the condition that the donor has clearly consented to the donation and the latter has no adverse implications for the donor's own health.

Additional Protocol concerning Biomedical Research

(Entry into force 1 September 2007)

The protocol specifies in detail the rules already established by the Convention, such as the consent of the persons taking part in a research operation and also their medical and legal protection. Any research project involving intervention on individuals must be examined by an independent ethical committee before research is carried out.

The protocol defines the conditions to be fulfilled where research involves persons incapable of expressing consent, or specific population groups such as prisoners or expectant/nursing mothers.

The protocol deal also with the research conducted in the States, which are not parties to the protocol, and protects the population of countries with emerging and developing economies against ethically unacceptable research (Article 29).

Additional Protocol concerning Genetic Testing for Health Purposes

(Opened for signature 27 November 2008)

The protocol stresses that appropriate quality of genetic services must be ensured, and details the rules related to genetic counselling, which should be offered prior to any predictive genetic testing. Given the sensitive nature of the information collected via genetic testing, the protocol recalls the importance of the respect for private life. It also establishes the rules that should be followed in case of genetic screening programs for health purposes.

Conclusion

The Oviedo Convention on Human Rights and Biomedicine was assigned two main tasks. Firstly, it was expected to lay down the ethical and legal principles that apply to any medical act and, secondly, to identify a number of principles that could be applied to the new biomedical techniques.

The impact of the Convention regarding the first task can be demonstrated by the legislative changes made by many countries in different parts of Europe since its negotiation. The principles established by the Convention have also had an influence on the drafting of certain other international documents with universal scope such as UNESCO's Universal Declaration on Bioethics and Human Rights.

Regarding the second task, the Convention and its Additional Protocols have yielded tangible results where it comes to laying down the rules for the protection of patients in the areas of medical research, the transplantation of organs and tissue as well as even genetics, despite the highly changing nature of this field.

However, some issues remain challenging. That is one of the reasons why some countries still encounter difficulties in ratifying the Convention.

About the Author

Ms. Ayşegül Elveriş – completed her Bachelor of Laws (LL.B.) degree at Galatasaray University in Istanbul, Turkey in 2002. Upon graduation, she attended Université Paris 1 Panthéon-Sorbonne in Paris, France, to do her masters degree in law (LL.M.). At Sorbonne, she focused on criminal law. She subsequently obtained a second masters degree in law at Robert Schuman University in Strasbourg, France, where she focused on human rights law. For the last six years, she has been working at the Council of Europe, where she started her career as a legal officer at the European Court of Human Rights. Subsequently, she worked for the Directorate General of Human Rights and Legal Affairs of the Council of Europe, in the department of the Social Charter. Currently, she is working at the Bioethics Division, Health and Bioethics Department, Directorate General of Social Cohesion. She is the Secretary of the Group of Specialists on Human Genetics.

Correspondence to: Ms. Ayşegül Elveriş, Bioethics Division, Health and Bioethics Department, Directorate General of Social Cohesion, Council of Europe, F-67075 Strasbourg Cedex, France, tel.: +33 (0) 390 21 54 90, email: aysegul.elveris@coe.int

THE OVIEDO CONVENTION FROM THE PERSPECTIVE OF DG RESEARCH

Lino Paula

*European Commission, DG Research, Governance and Ethics Unit, Brussels, Belgium**

The impact of the Oviedo Convention on EU legislation

When assessing the impact of the Convention on Human Rights and Bio-medicine – commonly known as the 'Oviedo Convention' – on EU legislation, it is important to note that the Council of Europe (CoE) and the European Union (EU) are distinct international organisations. The CoE has as members all EU Member States but also members that are not EU Member States, including a number of states from the easternmost part of Europe, such as Azerbaijan, Armenia and most importantly Russia.

In particular, it is important to note that the legal instruments of the two organisations take effect independently of each other. CoE Conventions as such are, therefore, not binding foundations for EU legislation. Furthermore, EU legislation takes effect in all EU Member States, whereas CoE conventions, such as the Oviedo Convention, only take effect in those Members States that have signed and ratified the respective Conventions and Protocols.

However, in EU Member States the conventions of the CoE can be applied via EU legislation in which reference is made to CoE Conventions. Examples of such EU legislation are Directive 98/79/EC on in vitro diagnostic medi-

cal devices [1], Directive 2004/23/EC [2] on setting standards of quality and safety for the donation, procurement etc. of human tissues and cells and Regulation (EC) No 1394/2007 [3] on advanced therapy medicinal products. For example, article 1.4 of Directive 98/79/EC states:

> "For the purposes of this Directive, the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States regulations on this matter."

Reference to the Oviedo convention is also made in EU legislation pertaining to the current Seventh Framework Programme for Research (FP7, 2007-2013), which is the EU's main instrument for funding research in Europe and also is the single largest research funding programme in Europe. Article 6 of the Decision n°1982/2006/EC [4], which decision adopt the Seventh Framework Programme, states that: "All the research activities carried out under the Seventh Framework Programme must be carried out in compliance with fundamental ethical principles."

The various EU Council Decisions pertaining to the Specific Programmes implementing FP7, describe these principles further in their Annexes. The description explicitly stipulates respect for the principles addressed in the Oviedo Convention and its Additional Protocols. The description is as follows (emphasis added) [5]:

> "During the implementation of this Specific Programme and in the research activities arising from it, fundamental ethical principles are to be respected. These include, inter alia, the principles reflected in the Charter of Fundamental Rights of the EU, including the following: protection of human dignity and human life, protection of personal data and privacy, as well as of animals and the environment in accordance with Community law and relevant international conventions, guidelines and codes of conduct, such as the Helsinki Declaration, **the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997 and its Additional Protocols**, the UN Convention on the Rights of the Child, the Universal Declaration on the human genome and human rights adopted by UNESCO, UN Biological and Toxin Weapons Convention (BTWC), International Treaty on Plant Genetic Resources for Food and Agriculture, and the relevant World Health Organisation (WHO) resolutions."

In this description explicit reference is also made to the principle of subsidiarity, meaning that researchers must conform to current legislation, regulations and ethical rules in the countries where the research will be carried out, including seeking approval of the relevant national or local ethics committees prior to the start of the RTD activities:

> "In compliance with the principle of subsidiarity and the diversity of approaches existing in Europe, participants in research projects must conform to current legislation, regulations and ethical rules in the countries where the research will be carried out. In any case, national provisions apply and no research forbidden in any given Mem-ber State or other country will be supported by Commu-nity funding to be carried out in that Member State or country.
>
> Where appropriate, those carrying out research projects must seek the approval of the relevant national or local ethics committees prior to the start of the RTD activities. An ethical review will also be implemented systematically by the Commission for proposals dealing with ethically sensitive issues or where ethical aspects have not been adequately addressed. In specific cases an ethical review may take place during the implementation of a project."

In summary, therefore, research funded by the EU must always be carried out in compliance with the provisions of the Oviedo convention [6]. In addition, other relevant EU legislation refers directly to the Oviedo convention. Thus, it is clear that the Oviedo Convention has had a concrete and significant impact on EU policies – and ipse facto on EU Member States – even on those EU Member States that have not `nationally` ratified the Oviedo Convention.

Future Challenges

As globalisation continues to take hold, research is also more and more becoming an international endeavour, with research teams throughout the world working together in complex networks on complex research questions. DG research of the European Commission also funds such international collaborative projects via FP7 – such projects of course include non-European countries that, therefore, have not ratified the Oviedo Convention or EU legislation. Moreover, such countries may actually have laws and regulations that are in conflict with the principles and provisions found in the Oviedo convention and EU legislation. The Commission's policy is that for research projects that are funded via FP7 and where part of the research is carried out in (non-EU) partner countries, also those parts being carried out outside the EU should adhere to the rules and regulations that govern FP7 projects. A similar provision is included in the Additional Protocol on Biomedical Research to the Oviedo Convention, whose article 29 reads:

> "Sponsors or researchers within the jurisdiction of a Party to this Protocol that plan to undertake or direct a research project in a State not party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based. Where necessary, the Party shall take appropriate measures to that end."

Clearly, upholding such compliance, especially in countries where research surveillance - and research ethics review infrastructures in particular - are fragile, remains a significant challenge for the future.

Equally challenging is the pace and complexity of current research. Scientific knowledge and publishing is still expanding exponentially and targeting new, multidisciplinary fields of research that transcend the traditional boundaries of scientific disciplines. Nanotechnology, biotechnology, information technology and the cognitive sciences are all inherently complex fields – both in terms of scientific and societal impact. – and that raise numerous thorny ethical issues. Moreover, these new fields give rise to even further `convergence` of science and technology; for example in a new field like synthetic biology, where nano, bio, info science and technology converge. Such new fields of science and technology are so complex and rapidly 'moving targets' that they are both hard to confine and define – in particular also legally. It is clearly a challenge to timely and adequately regulate such rapid and complex developments via CoE Conventions and Additional Protocols or EU Regulations and Directives. Such international legislation normally takes years to be agreed upon by the Member States, let alone to be implemented or, later, amended. Obviously, this is a challenge that has to be met as best as possible, which the

Oviedo Convention sets out to do, as it establishes fundamental principles applicable not only to daily medicine but as well to new technologies in the fields of biology and medicine. However, the Oviedo Convention itself also underscores the importance of complementing the legal approach with public dialogue. Article 28 of the Oviedo convention reads:

> "Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation."

The European Commission, and DG research in particular, supports numerous activities that encourage Europe-wide reflection and debate on science and technology and their relation with society and culture. Under FP7, it implements the `Science in Society` programme via a mix of initiatives that includes stimulating public dialogue about the ethical, legal and social aspects of science and technology, engaging all stakeholders at an early stage. [7]

Besides public dialogue, the legal approach can also be effectively supported by `soft law` instruments such as codes of conduct, Opinions of National Ethics Committees and exchange and coordination of best practise between Member States. The European Commission also initiates and supports such activities, and has for example published a Recommendation for a code of conduct for nanotechnology, [8] initiated a platform for exchange of information and best practise between national ethics councils (Forum of National Ethics Councils) [9] and established the European Group on Ethics in Science and New Technologies, which issues Opinions to the European Commission in connection with the preparation and implementation of EU legislation or policies. [10] In this regard, the activities of the Council of Europe and the European Union are mutually complimentary as well as reinforcing, and enabling Europe to reap the benefits of science and technology in a responsible, ethically sound way. The Oviedo Convention has proved to be a key pillar in this endeavour.

References

1. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. **2.** Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. **3.** Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004. **4.** Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013). **5.** 'ethical aspects' in the Annex of Council Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC, 2006/975/EC, furthermore 2006/976/Euratom and 2006/977/Euratom. **6.** However, for research carried out in a Member State without EU funding, and to the extent that it concerns research not affected by EU legislation that makes reference to the Oviedo Convention, the principles of the Oviedo Convention are binding only in those countries that have ratified the Convention. **7.** http://ec.europa.eu/research/science-society/ **8.** Commission Recommendation of 7 February 2008 on a code of conduct for responsible nanosciences and nanotechnologies research (notified under document number C(2008) 424) (2008/345/EC). **9.** http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=7510. http://ec.europa.eu/european_group_ethics/index_en.htm

** The views expressed in this paper are the sole responsibility of the author and do not necessarily reflect the views of the European Commission.*

About the Author

Dr. Lino Paula studied biomedical sciences and chemistry (M.Sc.) at Leiden University, and later obtained a M.A. in Biotechnology Law and Ethics from Sheffield University and a Ph.D. in Science and Technology Studies at the Vrije Universiteit Amsterdam. He has held positions as researcher at the Faculty of Veterinary Medicine, Department of Animals & Society of Utrecht University, as assistant professor Biology and Society at the Athena Institute of the Vrije Universiteit Amsterdam and as senior lecturer Biology and Society at the Institute of Biology of Leiden University. He furthermore was senior project officer technology assessment at the Rathenau Institute of the Netherlands. In these positions he has worked on several international projects and studies pertaining to the governance and ethics of the life sciences, in particular focusing on the use and impact of national ethics committees and public engagement in public policy. In 2006 he became policy officer at the Governance and Ethics Unit of DG Research, European Commission, in which position he is involved in the actions of the Science in Society programme (e.g. coordinating a European network of national ethics committees - NEC Forum) and the Socio-economic Sciences and Humanities of DG Research.

Correspondence to: Dr. Lino Paula, Science, Economy and Society - Governance and Ethics Unit, Directorate-General for Research, European Commission, Office SDME 7/80, B-1049 Brussels, Belgium, e-mail: lino.paula@ec.europa.eu

IMPACT OF THE OVIEDO CONVENTION AND ITS PROTOCOLS ON LEGISLATION IN WESTERN EUROPE, ESPECIALLY SWITZERLAND

Olivier Guillod

Institute of Health Law, University of Neuchâtel, Neuchâtel, Switzerland

Introduction

This short contribution is divided in three parts. The first will first provide a general overview of the legal and political stance in Western European countries as to the Oviedo Convention and its additional protocols.

The second part will try to assess the impact of the Oviedo Convention and its Protocols on western European Law. For that purpose, it will first explore whether Western European countries who have ratified the Convention have simultaneously issued reservations. Then, it will give a few hints as to new pieces of biomedical legislation in Western Europe, taking as an example the case of Switzerland.

The third part will sketch the role that the European Court of Human Rights in Strasbourg might play in the future of the Convention. Brief concluding remarks will end the contribution.

1. The legal stance in Western Europe

1.1 Western European countries and the Oviedo Convention

To date, twenty-three European countries have ratified the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (Convention on Human Rights and Biomedicine), that was initially adopted in Oviedo on April 4, 1997 [1]. Among them, only eight belong to what can be defined as Western Europe: Denmark, Greece, Iceland, Norway, Portugal, Spain, San Marino and Switzerland. Eleven more countries have signed the Oviedo Convention but have not ratified it. Among them, six from Western Europe: Finland, France, Italy, Luxembourg, Netherlands and Sweden which all signed the Convention on the very first day, *i.e.* on April 4, 1997. These figures also mean that nine countries from Western Europe have neither signed nor ratified the Oviedo Convention so far: Andorra, Austria, Belgium, Germany, Ireland, Liechtenstein, Malta, Monaco and the United Kingdom. As long as a country does not sign the Oviedo Convention, it cannot sign one of its additional protocols.

It would of course be interesting to know more precisely why major Western European countries like France, Germany, Italy and the United Kingdom, but also Austria, Belgium and Netherlands have not ratified, or not even signed the Oviedo Convention. But that would require a detailed analysis of the official positions in all these countries that cannot be carried out in the following few pages.

However, it is no secret that the material grounds for refusing to join the Convention have been very different for instance in Germany and in England. In Germany, the Oviedo Convention has been widely perceived as too liberal on some topics, for instance when the Convention allows carrying biomedical research with incompetent people, including minors (see art. 17). Even though there is no legal discrepancy between the Oviedo Convention and German law according to many legal writers [2], Germany is not yet politically ready to sign the Convention. In England on the contrary, the Oviedo Convention has been regarded as too restrictive on various points, for instance when Art. 18 para. 2 of the Convention prohibits the creation of human embryos for research purposes.

The situation has evolved in France over the last ten years: in 1998, the French Council of State (*Conseil d'Etat*) was against ratifying the Oviedo Convention, arguing that bioethical issues were evolving too rapidly to join a binding international agreement on the topic [3]. On April 9, 2009, the same Council of State adopted a new report in which it clearly states that he now favours a quick ratification by France of the Oviedo Convention [4]. At least two points explain the new stance of the Council of State: first of all, the legal developments in France since the passing of the so-called "*lois de bioéthique*" (for me, a contradiction in terms!) in 1994 has not shown any significant discrepancy with the Oviedo Convention; secondly, the role of the Oviedo Convention and its additional Protocols should be reinforced "*to fight against the risk of 'ethical deflation' at the international level*" [5].

1.2 Western European countries and the Additional Protocols

So far, four additional Protocols to the Oviedo Convention (as provided for in its article 31) have been adopted under the aegis of the Council of Europe. The first Protocol on the prohibition of cloning human beings [6] was opened for signature in Paris on January 12, 1998 and immediately signed by nineteen countries (it was in the aftermath of the Dolly story that shook public opinion throughout Europe). To date, the Protocol has been ratified by eighteen countries (it came into force on March 1, 2001) and signed by thirteen others. Five countries from Western Europe have ratified this Protocol: Greece, Iceland, Portugal, Spain and Switzerland. Nine countries have merely signed it: Denmark, Finland, France, Italy, Luxembourg, Netherlands, Norway, San Marino and Sweden.

The second additional Protocol was opened for signature in Strasbourg on January 24, 2002 and immediately signed by five countries. It deals with transplantation of organs and tissues of human origin [7]. This Protocol has been ratified by nine countries (it came into force on May 1, 2006) and signed by eleven others. Iceland is the only Western European country that has so far ratified the Protocol concerning transplantation of organs and tissues of human origin. Out of the 20 countries that have signed the Protocol, eight belong to Western Europe: Finland, Greece, Italy, Luxembourg, Netherlands, Portugal, Spain and Switzerland. In September 2008, the Swiss Government invited the federal Parliament to approve the Protocol [8]. On June 12, the Swiss Parliament actually approved it [9] but made three reservations because the Federal Act on organ transplantation is more liberal on three counts [10]. The Swiss Government is about to ratify formally the Protocol.

The third additional Protocol was opened for signature in Strasbourg on January 25, 2005 and immediately signed by nine countries. It deals with biomedical research [11]. The Protocol has been ratified by five countries and came into force on September 1, 2007; it has been signed so far by sixteen additional countries. No Western European country has ratified this protocol so far. Out of the 21 countries that signed the Protocol, only seven belong to Western Europe: Denmark, Greece, Iceland, Italy, Luxembourg, Portugal and Sweden.

The fourth additional protocol was opened for signature in Strasbourg on November 27, 2008 and immediately signed by three countries. It deals with genetic testing for health purposes [12]. This Protocol has so far been ratified by just one country (Slovenia; ratification of September 3, 2009) and couldn't therefore come into force (five ratifications are needed). The Protocol has been signed by four additional countries, among them three from Western Europe (Finland, Iceland and Luxembourg) and one from Eastern Europe (Moldova).

2. The impact of the Oviedo Convention in Western Europe

2.1 Can such an impact be assessed?

To assess in only a few pages the impact of the Oviedo Convention and its additional Protocols on legislation in Western Europe is an impossible task. It is extremely difficult indeed for an outside observer to ascertain whether a new piece of national legislation was actually influenced by the Oviedo Convention. It is even more difficult to assess with more details on which counts and to what extent national legislation was influenced by the Oviedo convention. What we know for sure is that any national law passed in a country that previously ratified the Oviedo Convention must be compatible with the Convention. We, therefore, can make a general presumption that the Oviedo Convention and its Protocols influenced national laws passed in a country that had previously ratified the Convention.

Due to space constraints and to the impossibility to draw any firm conclusions, I decided to limit my analysis to a

few countries which have ratified the Convention (Denmark, Greece, Norway, Spain and especially my own country, Switzerland) and to focus on two main issues:

- The content of reservations as well as of declarations made by Western European countries to the Oviedo Convention and its Protocols. It is an interesting point because it actually gives an idea of the extent to which national law is, or is not, deemed compatible with the Convention. It may also provide hints of possible changes to bring to the Oviedo Convention or its Protocols in the future.
- National laws which have been adopted in relationship to the process of ratifying the Oviedo Convention. By passing a law which content is made compatible with the Oviedo Convention, a country shows that it takes its international duties seriously and that it adheres to the substantial principles of the Convention.

2.2 The content of reservations made by Western European countries

Among the eight Western countries which have ratified the Convention so far, three have issued reservations: Denmark, Norway and Switzerland [13].

Denmark formulated one reservation pertaining to article 10 paragraph 2 (right to information of registered persons) because "*Danish legislation on registers provides that health information may be exempted from the registered person's right to information" and also because no access is granted to material provided "for the preparation of public statistics or scientific studies*" [14].

Denmark made a second reservation regarding article 20 paragraph 2, concerning the removal of regenerative tissue from a minor. Danish law exceptionally allows such removal not only for a brother or sister (as provided for in the Oviedo Convention) but also for his or her mother or father [15].

Norway made a similar reservation about article 20 paragraph 2 since Norwegian law allows the removal of regenerative tissue from a minor where the recipient is a child or parent of the donor or even in special cases, a close relative of the donor.

Switzerland made the same reservation as Denmark to article 20 paragraph 2. The Swiss Act on organ transplantation from October 8, 2004 allows the removal of regenerative tissues or cells from a minor when the recipient is his or her mother or father.

Switzerland also made a reservation pertaining to articles 19 and 20 of the Convention, because the Swiss Act of organ transplantation [16] does not expressly state the principle of subsidiarity of a removal on a living donor (*i.e.* subsidiarity with respect to removal on a dead donor).

Finally, Switzerland made a third reservation about article 6 sub-paragraph 3 which requires, when the patient does not have the capacity to consent, "*the authorization of his or her representative or an authority or a person or body provided for by law*". A number of cantonal laws indeed grant to the physician the power to make decisions for incompetent patients who do not have a representative. This reservation is merely temporary, until the entry into force of the reform of the Swiss civil code passed by Parliament on December 19, 2008 [17].

Overall, the small number of reservations made to the Oviedo Convention indicates the generally good acceptance of the content of the Oviedo Convention by the countries which decided to ratify it. But one might also think that countries which previously possessed national laws quite similar to the Oviedo Convention were most likely to ratify the Convention and didn't need to make any reservation.

As to the material content of the reservations, I would like to emphasize that four out of six countries formulating a reservation to the Oviedo Convention made it on the same point [18]. The internal law of Croatia, Denmark, Norway and Switzerland is less restrictive than the Oviedo Convention to the extent that it allows the removal of regenerative tissue from a minor for the benefit of his or her mother or father. Such a position, it is submitted, is quite reasonable and might inspire a future amendment to the Oviedo Convention.

There are too few reservations to the additional protocols to draw any solid conclusion. Netherlands declared when signing the first protocol (on the prohibition of human cloning) that it "*interprets the term 'human being' as referring exclusively to a human individual, i.e. a human being who has been born*".

Italy declared when signing the third protocol (on biomedical research) that it would not allow "*that a research which does not produce direct benefits to the health of the research participants be carried out on persons not able to give their consent and on a pregnant or breastfeeding woman*".

No reservation or declaration has been made so far in relation to the second protocol (on transplantation of organs and tissues of human origin) and fourth protocol (on genetic testing for health purposes). Switzerland will be the first exception. When approving the Protocol on transplantation and asking the Government to ratify it, the Swiss Parliament issued three reservations. The first two simply mirror the already mentioned reservations made to articles 19 and 20 of the Oviedo Convention (hereafter: OC). The third deals with article 10 of the Protocol allowing removal from a living donor only where there exists a close personal relationship between the recipient and the living donor or special conditions defined by law, in addition to the approval of an appropriate independent body. The Swiss Act on organ transplantation (see art. 12) does not include such requirements.

2. 3 Some new pieces of national legislation on biomedical issues

The process of ratifying the Oviedo Convention may have encouraged several countries to adopt internal laws that regulate more thoroughly various aspects of biomedicine. But it is fair to recall that biomedical issues have been hotly debated in most, if not all Western European countries years before the Oviedo Convention was adopted in 1997. Legislative work in some countries has undoubtedly influenced the substantial content of the Oviedo Convention and then the Oviedo Convention has had an impact on national laws. Present national legislation is therefore the result of many influences, irrespective of the country's attitude towards ratifying the Oviedo Convention. Without a detailed analysis of the whole legislative story of every single national law on biomedical topics, it is almost impossible to assess the true influence of the Oviedo Convention.

I will therefore limit myself to providing some objective information on a number of recent laws that were passed in various countries that have ratified the Oviedo Convention. Since I have been personally involved in expert committees preparing legislative work in the field of biomedicine in Switzerland, I will be able to make some more assertive comments regarding my own country.

Denmark (which ratified the Convention in 1999) has adopted many laws, decrees and orders in the following

ten years. The most significant piece of legislation in that area probably is the Health Act passed on June 24, 2005 [19]. This comprehensive law on health matters is divided in twelve parts. The third part deals for instance extensively with patients' rights (§ 13- 51), in full accordance with article 5 to 10 OC. Topics covered include for instance informed consent, living wills, self-determination with regard to biological materials, access to health files and professional confidentiality. The fourth part of the Danish Health Act is devoted to transplantation of organs and tissues from living persons and deceased persons (§ 52-56). Here again, the material rules are consistent with the Oviedo Convention.

Spain (which also ratified the Convention in 1999) has also adopted several significant laws on biomedical topics over the last ten years. In 2002, Spain passed for instance Law N° 41/2002 laying down basic rules concerning the autonomy of patients and their rights and duties with regard to clinical information and documentation [20]. That law deals with informed consent, advance directives, consent by proxy as well as with the right to privacy and the right to health information. Interestingly, Spain passed a Crown Decree in 2007 setting up a National Register of Advance Directives [21].

On July 3, 2007, Spain passed a very important Law N° 14/2007 on biomedical research [22]. Title I of the law contains general provisions; title II deals in a detailed way with research involving invasive procedures on human beings; title III regulates the donation and use of human embryos and foetuses, their cells, tissues, or organs; title IV is devoted to the procurement and use of human embryonic tissues and cells and other similar cells; title V deals with genetic analysis, biological samples and biobanks.

Greece (which ratified the Oviedo Convention in 1998 and signed the first three additional protocols on the prohibition of cloning, on organ and tissue transplantation and on biomedical research) also passed several laws in the field of biomedicine. On December 22, 2002, Greece adopted for instance Law N° 3089 on medically assisted human reproduction [23] that, inter alia, prohibits cloning (and punishes any violation of imprisonment up to 15 years).

Norway (which ratified the Convention in 2006) passed many important laws too. Before ratifying the Convention, it adopted Law N° 63 on patients' rights on July 2, 1999 [24]. That Law recognizes, among other rights, the right to health care, the right to give informed consent and the right to consult one's health files. Norway then adopted Law N° 79 of 13 December 2002 on the medical use of biotechnology which includes a prohibition of therapeutic cloning. In December 2003, Norway passed Law N° 100 on the use of biotechnology in human medicine [25] that deals with assisted fertilization, research on fertilized eggs and cloning, embryonic diagnosis, postnatal genetic testing and gene therapy.

The Norwegian "Patients' Rights Law" and the "Biotechnology law" have already been amended several times. Norway adopted still another important piece of legislation last year: Law N° 44 on research in the medical and health fields, passed on June 20, 2008 [26].

Switzerland has the reputation of taking quite seriously its international obligations and, therefore, to abide scrupulously by international law. As soon as an international agreement is ratified, it becomes an integral part of Swiss law and every citizen can claim the rights resulting from its provisions which have direct effect. Even before ratifying an international agreement, Swiss authorities are usually attentive to avoid creating legal discrepancies.

Public debate on biomedicine has a long story in Switzerland. It really started in the late eighties with the launching of a popular initiative asking for a constitutional amendment (adopted in a referendum by the Swiss citizens in May 1992) mandating the Swiss Confederation to legislate on genetics and on reproductive medicine. Another constitutional amendment was approved in a national referendum in 1999, which mandates the Swiss Confederation to legislate on organ, tissue and cell transplantation [27]. To complete the transfer of legislative power from the cantons to the Swiss Confederation in the biomedical area, the Swiss Parliament approved a third constitutional amendment on September 25, 2009, which mandates the Swiss Confederation to legislate on biomedical research [28]. All three constitutional amendments spell out a few substantial principles.

On September 12, 2001, the Swiss Government sent a report to the national Parliament inviting it to ratify the Oviedo Convention [29]. Simultaneously, a Bill on organ transplantation was introduced in Parliament. Since the Bill was deliberately more liberal than the Oviedo Convention on two points (organ donation from a living donor can be a primary option because it is proved to be more efficient than donation from a deceased person; the removal of regenerative tissue on a person unable to consent is allowed not only for a brother or sister but also for a mother, father or child of the donor), Parliament decided to pass the Act on transplantation in the first place and only afterwards to ratify the Oviedo Convention while making a couple of reservations. This explains why the ratification of the Oviedo Convention by Switzerland was remanded for several years, until July 2008 (the Convention went into force for Switzerland on November 1, 2008).

The numerous laws that Switzerland has passed on biomedical issues over the last ten years have been influenced by the Oviedo Convention even though the latter was not yet ratified. Here are the most important ones:

- the Federal Act on medically assisted procreation [30] from 2001 prohibits cloning a human being (like the first additional Protocol to the Oviedo Convention), prohibits the creation of embryos for research purposes (in accordance with art. 18 para. 2 OC), prohibits sex selection (as art. 14 OC does) as well as any intervention on the human genome (as required by art. 13 OC);
- the Federal Act on medicinal products [31] from 2002 regulates the clinical trials of new drugs in a way consistent with art. 16 and 17 OC;
- the Federal Act on research with embryonic stem cells [32] from 2005 implements the protection owed to embryos (in line with art. 18 para. 1 OC) ;
- the Federal Act on sterilisation [33] from 2005 includes stringent requirements for informed consent, especially from incompetent people, in accordance with art. 5 and 6 OC);
- the Federal act on human genetic testing from 2007 [34] is entirely compatible with the Convention. For instance, it prohibits explicitly any discrimination based on genetic traits (like art. 11 OC), regulates genetic tests for health purposes in a similar way as art. 12 OC and ensures the confidentiality of genetic data [as required by art. 9 OC);
- the Federal Act on organ, tissue and cell transplantation [35] from 2007 is also compatible with article 19 and 20 OC, except on the two points which were the object of two reservations from Switzerland when it ratified the Convention;

- the reform of the Swiss Civil Code [36], passed on December 19, 2008 (but not yet in force), introduces general rules on patients' rights in federal law that fully comply with art. 5 to 8 OC (informed consent, protection of persons not able to consent, protection of persons who have a mental disorder, informed consent in an emergency situation. The reform specifies who is legally empowered to give consent for an incompetent patient, thus putting and end to a large variety of cantonal solutions that occasionally were contrary to the Oviedo Convention (*e.g.* the solution to grant the power to decide to the treating physician). This reform also completely changes guardianship law and the legal regime of civil commitment in a mental hospital. The new art. 372 Civil Code goes even beyond art. 9 OC (which is allowed by art. 27 OC) when it asserts that advanced directives will have a binding effect for health professionals;
- the first draft of a Federal Act on biomedical research from 2009 aims at regulating the whole field of biomedical research in a way compatible with art. 15 to 17 OC.

Summing it up, the Oviedo Convention has had at least three kinds of influence on the internal legislative process in Western European countries. First of all, it has stimulated the political debate as well as the legislative work. Secondly, it has made more visible the existence of a common set of values based on human rights throughout Europe. And thirdly, it has contributed to a deeper awareness of the necessity to reinforce these values by passing national laws that are compatible with the Oviedo Convention.

3. A role for the European Court of Human Rights?

The Oviedo Convention was imagined as an extension of the European Convention for the protection of human rights and fundamental freedoms of November 4, 1950 for the specific field of biomedicine [37]. Now article 19 of the latter Convention provides that "[t]*o ensure the observance of the engagements undertaken by the High Contracting Parties in the Convention and the Protocols thereto, there shall be set up a European Court of Human Rights" which "shall function on a permanent basis*". Article 3. According to article 32, "[t]*he jurisdiction of the Court shall extend to all matters concerning the interpretation and application of the Convention and the protocols thereto*". Articles 33 and 34 provide that "*any High Contracting Party" as well as "any person, non-governmental organisation or group of individuals claiming to be the victim of a violation*" may refer to the Court. In addition, the Court "may, at the request of the Committee of Ministers, give advisory opinions on legal questions concerning the interpretation of the Convention and the protocols thereto (art. 47).

The Oviedo Convention does not contain provisions similar to those in the European Convention for the protection of human rights and fundamental freedoms giving jurisdiction to the European Court of Human Rights. On the contrary, article 23 OC states that "*Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention*". In addition, article 30 OC provides that on "*request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention*". Finally, article 29 OC empowers the European Court of Human Rights to give "*without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention*". Such an advisory opinion may be requested either by "*the Government of a Party, after having informed the other Parties*" or by the Steering Committee on Bioethics "*by a decision adopted by a two-thirds majority of votes cast*" (art. 29 OC).

The possibility given to the European Court of Human Rights to deliver advisory opinions on the interpretation of the Oviedo Convention may prove useful to circumscribe more precisely the meaning and scope of specific provisions such as article 21 on the prohibition of financial gain [38]. An advisory opinion would however have an impact only on countries that have ratified the Oviedo Convention. To the best of my knowledge, no advisory opinion has been asked so far to the European Court of Human Rights.

Even though the European Court of Human Rights has no direct jurisdiction on the application of the Oviedo Convention and its protocols by the contracting Parties, it may in an indirect way influence national law in Europe even beyond the contracting Parties. For the last few years, the Oviedo Convention has been occasionally integrated in the decisions made by the European Court of Human Rights on alleged violations of the European Convention for the protection of human rights and fundamental freedoms. In other words, the Oviedo Convention is sometimes used by the European Court of Human Rights as a tool to interpret the European Convention for the protection of human rights and fundamental freedoms, especially articles 2 (right to life) and 8 (right to respect for private and family life). All 47 countries which have ratified the European Convention for the protection of human rights and fundamental freedoms must conform to the rulings of the European Court of Human Rights and, where needed, adapt their internal legislation.

It is interesting to note that the Oviedo Convention was mentioned as part of the relevant international law even in some cases involving a country that did not ratify the Oviedo Convention. For instance, in the case of *Glass v. United Kingdom*, the European Court mentions articles 5 to 9 OC as part of the "*relevant international material*" [39] regarding informed consent. In the case of *Vo v. France*, the Court not only mentions several provisions from the Oviedo Convention but also quotes excerpts from the explanatory report [40]. It also refers to the additional Protocol on the prohibition of cloning human beings as well as the draft Protocol (at the time) on biomedical research [41] in order to determine if there is an accepted position in international law as to the legal status of the human embryo or foetus.

It will be interesting to follow closely the development of the case law from the European Court of Human Rights to assess whether the Oviedo Convention will be used more and more frequently to state the present content of accepted international law.

I personally expect the Court to rely increasingly on the Oviedo Convention to interpret especially article 8 of the European Convention, i.e. the right to respect for private and family life, which served as a basis for the European Court of Human Rights in its rulings on informed consent as well as on confidentiality of medical records. By influencing the interpretation of the European Convention for the protection of human rights and fundamental freedoms, the Oviedo Convention may therefore have an indirect impact on the law of all 47 countries that have ratified that Convention.

4. Concluding remarks

The Oviedo Convention expresses the prevalent view in Western Europe on the appropriate legal answers to contemporary biomedical issues. Approximately 35% of Western European countries have ratified it and 25% have signed it, leaving 40% of Western European countries completely outside. A convincing sign that the Oviedo Convention expresses balanced choices on biomedical topics can be seen in the fact that a few countries have refused to sign it either because it was too liberal or because it was too restrictive.

Each new ratification of the Oviedo Convention is a further recognition (and reinforcement) of a set of common European values based on Human Rights. I believe it is of great importance to reaffirm our European approach of biomedical issues based on human rights since we live in a globalized world where a clear "imperialism" of American bioethics and economic power threatens to eclipse all other views. One can therefore hope that the "big" Western European countries (like France, Germany and the United Kingdom) that haven't so far ratified the Oviedo Convention will do so in the near future. For that purpose, it would be of the utmost importance that reputed people or institutes (from the political, economic or academic circles) in these countries get actively involved in a campaign to promote the Oviedo Convention and its ratification.

One should also recall that the Oviedo Convention is the ground floor of the common European "biolaw" house. Additional floors, called Protocols, are still under construction. To access them, a country needs to go first through the ground floor but then it can take the elevator to go to any floor, possibly leaving aside some of the floors. When entering the house, a country cannot ask to change its fundamental structural elements but it can suggest changing the interior design. In other words, the ethical discussion is not closed when a country joins the Oviedo Convention but is on the contrary stimulated. That process of constant reassessment may lead to a proposal to modify the Convention. As provided for in article 32 para. 4 OC, the CDBI (Steering Committee on Bioethics) shall examine the Convention no later than five years from its entry into force (December 1, 1999) and thereafter at such intervals as the CDBI may determine.

The legal and political process of ratifying the Oviedo Convention is itself of great value for any European country. It compels the country to scrutinize its national laws on biomedical issues that are fundamental for the future of mankind and to assess their rationale, compared to the provisions of the Oviedo Convention.

References

1. CETS N° 164. **2.** See e.g. Jochen Taupitz, Landesbericht Deutschland, *in* J. Taupitz (Ed.), The Convention on Human Rights and Biomedicine of the Council of Europe, Berlin-etc. 2002, p. 409, 485. **3.** Etudes et documents du Conseil d'Etat n° 49, Paris 1998, p. 88. **4.** La révision des lois de bioéthique, Paris 2009, p. 124. **5.** *Ibidem* ("le rôle de cette convention et de ses protocoles doit au contraire _tre renforcé pour lutter contre le risque de « moins-disant » éthique _ l'échelon international »). **6.** CETS N° 168. **7.** CETS N° 186. **8.** Feuille fédérale 2008, p. 7229 (http://www.admin.ch/ch/f/ff/2008/7229.pdf). **9.** Feuille fédérale 2009, p. 4007 (http://www.admin.ch/ch/f/ff/2009/4007.pdf). **10.** See below the text in connection with the reservations made to the Oviedo Convention. **11.** CETS N° 195. **12.** CETS N° 203. **13.** Denmark also declared that until further notice, the Convention should not apply to the Faroe Islands and Greenland. **14.** For the text of all reservations made to the Oviedo Convention, see the website of the Council of Europe: http://conventions.coe.int/Treaty/Commun/ListeDeclarations.asp?NT=164&CM=8&DF=24/10/2009&CL=ENG&VL=1. **15.** Croatia made the same reservation to article 20 paragraph 2 because Croatian law allows the removal of regenerative tissue from a minor for the benefit of his or her parents. **16.** Recueil systématique 810.21 (http://www.admin.ch/ch/f/rs/c810_21.html). **17.** Feuille fédérale 2009, p. 139 (http://www.admin.ch/ch/f/ff/2009/139.pdf). **18.** Turkey also made a reservation to article 20 paragraph 2, but in an opposite direction: Turkish law completely prohibits the removal of regenerative tissue from a person who does not have the capacity to consent. Since Turkish law grants a wider measure of protection to persons not able to consent to organ and tissue removal, it is compatible with the Oviedo Convention, according to the latter's article 27. **19.** Lovtidende, 2005, Part A, 25 June 2005, N° 92, p. 3914 ff. **20.** Boletín Oficial del Estado, 15 November 2002, N° 274, p. 40126 ff. **21.** Boletín Oficial del Estado, 15 February 2007, N° 40, p. 6591 ff. **22.** Boletín Oficial del Estado, 4 July 2007, N° 159, p. 28826 ff. So far, Spain has not signed the additional protocol on biomedical research. **23.** http://www.bioethics.gr/media/pdf/biolaw/human/law_3089_en.pdf. **24.** Norsk Lovtidend, Part I, N° 14, 30 July 1999, p. 1630 ff. **25.** http://www.lovdata.no/all/nl-20031205-100.html. **26.** http://www.lovdata.no/ltavd1/filer/nl-20080620-044.html. **27.** It means that until the late nineties, topics such as reproductive medicine, gene testing and transplantation were covered in Switzerland by cantonal laws, opening the way to 26 potentially different legislations on such a small piece of land (circa 40'000 km^2). **28.** Feuille fédérale 2009, p. 6005 (http://www.admin.ch/ch/f/ff/2009/6005.pdf). The constitutional amendment must still be approved by the Swiss citizens in a national referendum that will be held on March 7, 2010. **29.** Feuille Fédérale 2002, p. 271 (http://www.admin.ch/ch/f/ff/2002/271.pdf). **30.** Recueil systématique 810.11 (http://www.admin.ch/ch/f/rs/c810_11.html). **31.** Recueil systématique 812.21 (http://www.admin.ch/ch/f/rs/c812_21.html). **32.** Recueil systématique 810.31 (http://www.admin.ch/ch/f/rs/c810_31.html). **33.** Recueil systématique 211.111.1 (http://www.admin.ch/ch/f/rs/c211_111_1.html). **34.** Recueil Systématique 810.12 (http://www.admin.ch/ch/f/rs/c810_12.html). **35.** Recueil systématique 810.12 (http://www.admin.ch/ch/f/rs/c810_21.html). **36.** Feuille fédérale 2009, p. 139 (http://www.admin.ch/ch/f/ff/2009/139.pdf). **37.** The preamble of the Oviedo Convention expressly refers to the 1950 Convention. **38.** "The human body and its parts shall not, as such, give rise to financial gain". **39.** Decision from March 9, 2004, § 58. **40.** Decision from July 8, 2004, § 35f. **41.** Id., § 37f.

About the Author

Prof. Olivier GUILLOD is founder and director of the Institute of Health Law, University of Neuchâtel, Neuchâtel in Switzerland. He serves also as professor of private law and health law, University of Neuchâtel, invited professor of health law, University of Lausanne, and invited professor of private Law, University of Fribourg (Switzerland), member of the Swiss National Advisory Committee on Biomedical Ethics since its creation in 2001, member of the Swiss Academy of Medical Sciences, consultant of several Swiss cantons on health law issues, member of the steering committee of the francophone network in health law, chairman of the Cantonal Committee on addictions. He was invited speaker to numerous conferences in Europe, Northern America and Africa. Author of many books and papers on health and biomedical law topics.

Correspondence to: Prof. Olivier GUILLOD, Institut de droit de la santé, Université de Neuchâtel, 26 avenue du 1er mars, 2000 Neuchâtel, Switzerland, e-mail: olivier.guillod@unine.ch

IMPACT OF THE OVIEDO CONVENTION AND ITS PROTOCOLS ON LEGISLATION AND PRACTICES IN SLOVENIA [1]

Jože Trontelj

Slovenian National Medical Ethics Committee, Ljubljana, Slovenia

Slovenia has had a long and respectable history of medical ethics. As a new independent state, it needed a lot of new legislation. Moreover, new developments in medicine, science and society presented new challenges. It was therefore extremely important to have, in addition to the longstanding tradition in medical ethics and moral philosophy, some reliable external points of reference to the present international standards.

The Council of Europe has offered such reference. The European Convention on Human Rights has set standards over much of Europe. It must be admitted that it had little impact in the post Post-second World War Yugoslavia, particularly during its first decades. Nevertheless, respect for human rights gradually increased, and the situation improved considerably over the years.

Even in the years of oppression, however, ethical standards in medicine were surprisingly high. This not only applied to the individual doctor-to-patient relationship and standards of care, but also to the systemic issues, such as equity and fairness in distribution of resources. In fact, good medical care for everybody was one of the state priorities.

Precisely the historical background of the unsatisfactory human rights situation over many years in the Post-second World War Yugoslavia may have contributed to some kind of ethical hunger at the end of the Communist Epoch. This accounts for a part of the great respect that ethical projects of the Council of Europe enjoy in Slovenia. Effects are seen in legislation and medical practice, in biomedical sciences and in other fields concerned. Unfortunately I can say less about public perception of ethical issues, as only indirect conclusions can be drawn from the limited evidence available, and in the absence of systematic studies of public opinion.

Slovenia has been participating in bioethical projects of the Council of Europe since 1995. I shall mainly refer to the work of the CDBI and to the main project, discussed in this meeting, i.e. the Oviedo Convention. So I shall not touch on the very important parallel work of other bodies, especially the Parliamentary Assembly and the Committee of Ministers, in spite of its exceptional importance, for example in the field of the rights of terminally ill and of palliative care.

First of all, I must express my appreciation of the Slovenian Governments and Parliament, who understood the exceptional value and significance of ethics in the life of a nation and possessed the wisdom to join, practically without reservations, the European efforts in promoting the international ethical standards. This wisdom and this awareness have led Slovenia to be among the first countries to ratify the Oviedo Convention and its Additional Protocols. These ethical and legal instruments were an important source of guidance to our legislators in formulating the legal framework and the medical professionals in aligning their practice with the European ethical standards.

Finally, in public debate on the contentious ethical issues, the undisputed reputation of the CDBI and other bodies of the Council of Europe provided an authority in ethical opinion which to my knowledge has never been publicly questioned.

I would now like to come to certain pieces of legislation and the consequent legal and medical practice where the Oviedo Convention and its Additional Protocols played an essential role.

Perhaps the most important of all is the Law on Patient's Rights. A number of provisions in the Oviedo Convention were directly incorporated into the Law. Other legal and ethical substance was carefully aligned with the principles in the Convention. Such were, in particular, provisions regarding consent of the patient to therapeutic interventions, as well as research. Special attention was given to medical decisions about patients unable to consent. The Convention's article on due respect for previously expressed wishes was elaborated in the provisions on advance directives. The Oviedo Convention in this article remains less decisive than our legislator would like to see. The Parliament then chose the suggested formulation of the National Medical Ethics Committee that the treating doctor should consider, in most situations, the patient's wish as an important but not the only factor in deciding between life preserving and palliative treatment. The doctor should however abandon attempts at prolongation of life when this would not give hope for improvement of health or relief of suffering.

The provision on compensation for undue damages sustained during treatment, previously unfortunately rather neglected in Slovenian health care practice, has been elaborated in considerable detail in the new law and efficient mechanisms have been put in place.

The Slovenian Law on organ transplantation was based on the corresponding Additional Protocol to the Oviedo Convention. In fact, it drew upon the draft of the Protocol, since at that time the final version was not yet ready. Among the important principles was the very limited set of situations when for example a kidney can be explanted from a living donor. At a later stage, the authority of the Oviedo Convention and the Transplantation Protocol was helpful when yellow press brought up a doubt that brain dead patients are really dead. Most of the arguments for this doubt could be rejected as obscure, but some come from more serious, although not fully credible sources. Currently, close relatives of brain dead patients have the right to refuse removal of organs. Now there is an attempt at changing the law and follow the opting out principle; i.e., the patient is considered to have had no objection unless written statement or witnesses say otherwise.

The working group that drafted the Law on Infertility Treatment and Biomedically Assisted Reproduction unfortunately was not much helped by any recent ethical-legal instrument of the Council of Europe, although an older document – "Report on human artificial procreation Principles set out in the Report of the ad hoc Committee of experts on progress in the biomedical sciences (CAHBI, published in 1989)" proved valuable. In its present form, the Slovenian law gives priority to the right of the future child to be born into a stable family environment, favourable for its development, rather than serving the sole interests of the prospective parents. So, it was with real regret when we learned that it was not possible to develop a meaningful minimum of protective principles in questions of artificial procreation in the form of a Protocol to the Convention.

The Oviedo Convention stipulates, in its Article 28, public debate on ethical issues raised by the new developments in biomedical sciences. In Slovenia such debate preceded or accompanied the parliamentary discussions of many laws containing bioethical issues. It was particularly vivid when the use of human embryos for research was discussed in relation to the 7th Framework Program

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.

About the Author

Prof. Jože Trontelj, born in 1939 in Slovenia. Medical Doctor and Doctor of Neurosciences, Professor of Neurology at the Ljubljana Medical School. Author or co-author of over 150 papers in journals, over 30 book chapters and 2 books, mainly on electromyography and physiological basis of neurological disorders. Over 70 publications on bioethical issues. Since 1991, member of the Slovenian Academy of Sciences and Arts, since 2008, its President. Since 1995, Chairman of the National Medical Ethics Committee of Slovenia, and Slovenian delegate to the Steering Committee on Bioethics (CDBI) of the Council of Europe. Member of the Working Party that drafted the Additional Protocol to the Convention on human rights and biomedicine, on biomedical research.

Correspondence to: Prof. Joze Trontelj, Chairman, Slovenian National Medical Ethics Committee, Zaloska 7, SI-1525 Ljubljana, Slovenia, e-mail: joze.trontelj@kclj.si

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

Givi Javashvili

Family Medicine Department, Tbilisi State Medical University; National Council on Bioethics; Tbilisi, Georgia

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.

About the Author

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.

Correspondence to: Professor Givi Javashvili, Family Medicine Department, Tbilisi State Medical University; Chairman of the National Council on Bioethics, 29 Chavchavadze Avenue, 0179 Tbilisi, Georgia, e-mail: gjavashvili@tsmu.edu

THE OVIEDO CONVENTION: CHALLENGES AND PERSPECTIVES OF ITS ADOPTION IN ARMENIA

Armen Vardapetyan, Igor Madoyan

National Center of Bioethics, Yerevan, Republic of Armenia

The history of bioethics, as is known, counts 40-50 years. In Armenia, ideas on bioethics started to spread in the 90ies of the last century. Want to note, that historically, the period coincided with elaboration and adoption of the Convention on Human Rights and Biomedicine. Still, up to date, the process of bioethics development in Armenia kind of proceeds parallel to the Oviedo Convention and does not intersect. Why is it so? I would try to briefly state the main reasons of this phenomenon.

About 7-10 years ago, not only people not related to healthcare but the majority of biologists, physicians, philosophers, lawyers in Armenia had the least notion of bioethics, moreover, had never heard this term. To be fair enough, it should be noted that a similar situation was observed in a number of countries of Eastern Europe and former Soviet Republics. Bioethical ideas started to sprout in Armenia due to enlightening activities by individual enthusiasts, just a few of them. It is through individual talks, round tables, seminars, newspapers and television, through attempts to convince state officials in the importance of and the need in introducing bioethical norms and standards, these people were able to raise interest towards ethical aspects of biomedicine in Armenia.

Non-for-profits with missions in bioethics started to emerge at the beginning of the century. Cooperation between those, on one hand and state structure, on the other becomes tighter, and, I would even mention, more reliable. Armenia is gradually increasing activism within bioethical structures of international organizations (Council of Europe, UNESCO, European Commission, Forum of ethical committees of NIS, WHO, etc). Special courses are delivered at Universities; ethical boards are created within research institutes and universities.

Up to date, the country lacks a solid and targeted public policy and a state program on bioethics development though the interest towards bioethics in Armenia is increasing and the importance is out of doubt. The lack of the state program on the ethics of biomedical researches, from my perspective, is one of the major reasons of lack of correlation between the process of bioethics development in Armenia and the adoption of the Oviedo Convention by the Council of Europe.

Another reason is the lack of an appropriate legislative framework. The main thesis of the Oviedo Convention and its additional protocols puts the interests of a human being above the interests of science and society. Republic of Armenia's Constitution reads: "*A human being cannot undergo medical or scientific experiments without his/her consent*". Still, we have not been able to locate a provision defining a defending mechanism for this provision in any of the laws adopted during the last decade. On the other hand, the same laws do not contradict basic human rights postulates. Therefore, the paternalistic model of physician-patient relationship dominates over the autonomous model everywhere in Armenia. To phrase it otherwise, the bioethical component is missing in the laws. This means that the Armenian laws reflect provisions on patients' rights without taking into account provisions of the Convention on Bioethics. This is, actually, a conclusion drawn from the questionnaire from Armenia on the Impact of the Oviedo Convention. I am not going to heavily concentrate on a thorough analysis of the legislation as it is more important to present a real situation on the perspectives of Convention implementation at this seminar. Getting back to the questionnaire, it should be noted that the responses outlined that the Armenian legislation to some extent reacts to the challenges brought forth by the scientific technological achievements in biomedicine. But, regretfully, an impression is made that the ethical and legal aspects of the Oviedo Convention are not considered to the maximum possible extent while developing legislation. The same conclusion is drawn from the response of the Republic of Armenia Ministry of Justice on the Questionnaire on Recommendation (2004). Thus, here is another important reason for "parallel" co-existence of the national legislation and the Oviedo Convention – shortage of professionals and insufficient awareness on bioethics among public at large.

Bioethics, as it seems to me, is to be viewed as a scientific-educational system and, simultaneously, a social movement. In case of a social movement, it has to lay social and psychological grounds for the perception of norms and principles of bioethics by the Armenian society. It is obvious that all vehicles provided by the state should be used to popularize, propagate and publicize those. As a scientific-educational system, bioethics should ensure creation of a core of Armenian experts in bioethics. Preparation of specialists could be organized according to two models. The first model implies existence of infrastructure (university departments, chairs, centers, etc.) with major in bioethics (bachelor's degree). The second model would be an opportunity for representatives of diverse specializations (biologists, medical doctors, lawyers, and philosophers, theologians) to pursue post graduate degree in biomedical ethics. In the near future, I am confident, an acute need in experts in bioethics will arouse in the Parliament and the Government of the Republic, in the courts, insurance companies, ethical committees on different levels, not to mention the systems of healthcare and education. Even today, they, the experts can have their input to the draft law of the Republic of Armenia on Healthcare.

The main conclusion we draw from the above mentioned is as follows: unfortunately, practical mechanisms of ethical and legal regulation in the field of biomedicine are not existent. Of course, forms of moral and legal control bear national specifics and could not be viewed independent of ethno-cultural tradition of a concrete nation. Armenia has rich experience and ancient history in the field of medicinal ethics. Therefore, when we talk about bioethics development in Armenia, by all means, should consider peculiarities of the national identity and national legislation. At the same time, universal norms and principles of bioethics are successfully applied in many countries of the world. Since Armenia is a part of the global and of the European communities in particular, I am confident that my country sooner or later will sign such an important document as the Oviedo Convention is.

About the Authors

Dr. Armen Vardapetyan. In 1996 – 2001, he studied at the Armenian Agricultural Academy Department of Veterinarian Sciences. In 2001 – 2004, he took a post graduate course at the Chair of Surgery of the same Academy. In 2004 he defended his doctoral thesis and received PhD. in veterinary medicine. Currently he teaches at the Yerevan State University's Department of Biology. Areas of his scientific interest are the issues related to humanistic and bioethical education.

Dr. Igor Madoyan. In 1971 – 1976, he studied at the Yerevan State University Department of Biology. In 1976 – 1979, he took the post graduate course at the Institute of Molecular Biology of the USSR Academy of Sciences (Moscow). In 1980, he defended his doctoral thesis and received PhD. in biology. In 1997 – 2000, he passed the course for the doctoral degree in bioethics at the Institute of Philosophy of the Russian Academy of Sciences in Moscow. For the last six years, Mr. Madoyan is directing the National Center of Bioethics in Yerevan, Armenia.

Correspondence to: Dr. Armen Vardapetyan, PhD., National Center of Bioethics, 24-14 Sayat-Nova ave, 0001 Yerevan, Armenia, e-mail: miagra@rambler.ru, vardapetyan_a@rambler.ru

IMPACT OF THE OVIEDO CONVENTION AND ITS PROTOCOLS ON NATIONAL LEGISLATION IN CROATIA

Dubravka Šimonović[1], Ana Borovečki[2]

[1]Department for International Organizations and Human Rights, Directorate for Multilateral Affaires, Ministry of Foreign Affaires and European Integration of the Republic of Croatia; [2]Department of Social Medicine and Organization of Healthcare, Andrija Štampar School of Public Health, School of Medicine, University of Zagreb; Zagreb, Croatia

The Republic of Croatia started to follow the work of the Steering Committee on Bioethics (CDBI) as an observer in 1995 when it was entrusted with elaborating the first framework convention on bioethical issues. The Republic of Croatia joined membership of the Council of Europe on 6 November 1996 and assumed an active role in the drafting process that resulted in the adoption of the Convention for the protection of human rights and dignity of human beings with regard to the application of biology and medicine: the Convention on Human Rights and Biomedicine on November 19, 1997, or the Oviedo Convention. It entered into force ten yeas ago - on December 1, 1999, and started out as the first legally binding instrument in this field that connects human rights and biomedicine. The last decade of its existence and implementation is an appropriate time frame to assess its influence in harmonization legal standards in this field at the national and international levels. At the international level the Oviedo convention has produced an important impact on standards in the same filed adopted by other organizations like the UN and UNESCO.

We will focus on its impact at the national level in the Republic of Croatia. The Republic of Croatia started the process of its acceptance by signing the Oviedo Convention and the Additional Protocol on the Prohibition of Cloning of Human Beings in Budapest, Hungary, on May 7, 1999. The ratification process required more time and the Croatian Parliament ratified the Oviedo Convention and the Additional Protocol on the Prohibition of Cloning Human Beings on July 14, 2003. It also ratified the Additional Protocol to the Convention on Transplantation of Organs and Tissues of Human Origin that had been adopted while the process of ratification was ongoing (1).

Since its ratification in 2003 and the publication of its translated text in the Official Gazette, the Oviedo Convention has formed part of the internal legal system of the Republic of Croatia with legal effect stronger than national law. Article 140 of the Croatian Constitution (2) declares: *„International agreements concluded and ratified in accordance with the Constitution and made public, and which are in force, shall be part of the internal legal order of the Republic of Croatia and shall be above law in terms of their legal effects."*

Courts apply international treaties directly when they decide on issues concerning the protection of human rights of an individual. Article 5 of the Courts Act (3) provides: *„Courts rule according to the Constitution and the laws. Courts also rule according to the international treaties which are part of Croatian legal order."*

Upon its ratification, the Republic of Croatia made one reservation regarding Article 20 of the Convention on Human Rights and Biomedicine dealing with the protection of persons not able to consent to organ removal. Croatia made its reservation to this article, because in the Republic of Croatia the removal of regenerative tissue (like bone marrow) is permitted in the cases of donation from a minor to parents by the Law on Retrieval and Transplantation of Human Body Parts for Medical Treatment as amended in 2009 (4).

In the Republic of Croatia numerous laws have been adopted after the ratification of the Oviedo Convention and its Additional Protocols. In the legislative process they are aligned with the relevant provisions of the Oviedo Convention. In some cases national law provisions replicate or reflect certain provisions from the Oviedo Convention.

For example, the 2004 Law on Protection of Patients' Rights (5) also reaffirms the basic principles of the Convention with the introduction of informed consent as an essential prerequisite to any medical procedure except in emergency cases, with the protection of privacy and the right to information and the protection of the patients participating in medical research. Article 16 and Article 17 of the Convention regarding the protection of persons participating in medical research have been fully replicated in this law.

As a way of implementing specific provisions of the Additional Protocol to the Convention on the Prohibition of Cloning Human Beings we could mention the adoption of the 2004 amendments to the Criminal Code (6) that sanction the cloning of human beings. This new provision reaffirms the prohibition of the cloning of human being as provided in the Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings, and it additionally provides for a prison term sanction for a perpetrator of such a crime.

Another example is the 1997 Law on the Protection of Persons with Mental Disorders (7) and its amendments that replicate Article 7 of the Convention entitled "Protection of persons who have a mental disorder", stating the following: *"Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health."*

Even if they are not yet ratified, instruments like the Additional protocol to the Convention on Human Rights and Biomedicine concerning biomedical research have influenced national legislation. For example, the Republic of Croatia adopted in 2007 the new Law on Drugs and the Regulations on Clinical Research and Good Clinical Practice (8, 9) which is in line with this Protocol although it has not yet been ratified by the Croatian Parliament.

The impact of the Oviedo Convention is also visible in more general human rights legislation like the Croatian Anti-discrimination Law (10), which entered into force on January 1st 2009. This law prohibits various forms of discrimination in different areas of life, including expressly prohibiting discrimination on the ground of genetic heritage. With this provision of the Anti-discrimination Law Croatia has introduced Oviedo Convention standard in its Anti-discrimination Law confirming the prohibition of discrimination against human beings on the ground of genetic heritage as a human rights standard.

The last example of the impact of the Oviedo Convention is adoption of the new Law on Medical Fertilization (11). Some articles of this Law replicate the standards contained in the Oviedo Convention, like Article 20 that provides for the prohibition of sex selection except in cases of severe genetic disorders, and Article 31 that provides for an explicit prohibition of the creation of embryos for research purposes.

In conclusion, the Oviedo Convention and its two Additional Protocols ratified by the Republic of Croatia are incorporated in the Croatian legal system and replicated in different implementing laws. The other two Additional Protocols, namely the Additional Protocol on Biomedical Research and the Additional Protocol concerning Genetic Testing for Health Purposes, that are still awaiting the ratification process, are taken into consideration when legislation on similar matter is drafted.

At the level of the Council of Europe we could conclude that the Oviedo Convention and its Additional Protocols set new standards in this field of human rights and biomedicine. The next step should be their increased acceptance by the Member States of the Council of Europe what would result in a greater harmonization of national standards in this field. At the same time, stronger focus on its implementation is needed, and elaboration of the reporting and monitoring process could be envisaged by the Steering Committee on Bioethics in the next decade.

References

1. Law on Ratification of Convention on Human Rights and Biomedicine [in Croatian]. Narodne novine – Medunarodni ugovori. 13/03. **2.** Constitution of the Republic of Croatia [in Croatian]. Narodne novine. 41/01, 55/0. **3.** Courts Act [in Croatian]. Narodne novine.150/05. **4.** Law on Retrieval and Transplantation of Human Body Parts for Medical Treatment [in Croatian]. Narodne novine. 177/04, 35/09. **5.** Law on Protection of Patients' Rights [in Croatian]. Narodne novine. 169/04. **6.** Law on the Changes and Amendments to the Criminal Code [in Croatian]. Narodne novine.105/04. **7.** Law on Protection of Persons with Mental Disorders [in Croatian]. Narodne novine. 111/97, 128/99, 79/02. **8.** Law on Drugs [in Croatian]. Narodne novine. 71/07. **9.** Regulations on Clinical Research and Good Clinical Practice [in Croatian]. Narodne novine.121/07. **10.** Antidiscrimination Law [in Croatian]. Narodne novine.85/08. **11.** Law on Medical Fertilization [in Croatian]. Narodne novine. 88/09.

About the Authors

Ms. Dubravka Šimonović PhD. – holds a PhD. in the field of law. Her doctoral thesis was on legal regulation of medically assisted procreation. A career foreign service servant, she heads the Human Rights Department in the Ministry of Foreign Affairs. She has been an expert on the Steering Committee on Bioethics, its Vice-Chair from 2001-2003 and Chairperson from 2003-2005 and representative of the Steering Committee on Human Rights. She is a member of the UN Committee on the Elimination of Discrimination Against Women since 2003 and was its Chairperson from 2007 to 2008. She was Chairperson of the Council of Europe Task Force to Combat Violence Against Women (2006-2008) and she is Co-Chair of the Committee on Preventing and Combating Violence against Women and Domestic Violence (CAHVIO).

Ms. Ana Borovečki, MD, PhD. – graduated medicine from the School of Medicine, University of Zagreb, Croatia and got bachelor degree in philosophy and comparative literature from the School of Philosophy, University of Zagreb, Croatia. In 2004 she got European Master of Bioethics degree from the Catholic University of Leuven, Belgium. In 2007 she got PhD degree from Radboud University in Nijmegen, the Netherlands. The title of the thesis was "Ethics Committees in Croatia". In 2008 she obtained specialist degree in clinical pharmacology and toxicology and in 2009 Master of Public Health degree from School of Medicine, University of Zagreb. She works at Andrija Štampar School of Public Health, School of Medicine, University of Zagreb, as Assistant Professor.

Correspondence to: Dr. Ana Borovečki, "Andrija Stampar" School of Public Health, Zagreb Medical School, Rockefellerova 4, 10000 Zagreb, Croatia, e-mail: abor@mef.hr

COUNTRY REPORT – ESTONIA

Kristi Lõuk

Estonian Council on Bioethics, Tartu, Estonia

The system of ethics review boards was created in Estonia in 1990. The national ethics council, Estonian Council on Bioethics was established in April 1998 with the help of Council of Europe via DEBRA programme. During the DEBRA programme, three seminars (two in 1998 and one in 2003) were organised in Tartu for physicians and for other people who were involved in the field of biomedical research. Among the topics addressed were role and function of ethical review boards, research on children, and the relationship of bioethics and law. Each seminar had more than hundred participants.

Estonia signed the Oviedo convention in April 1997, and ratified it in December 2001. The additional protocol on the Prohibition of Cloning of Human Beings was signed in January 1998, and ratified in December 2001. The additional protocol concerning Transplantation of Organs and Tissues of Human Origin was signed in January 2002, and ratified in July 2003. The two other additional protocols, i.e. the Additional Protocol concerning Biomedical Research and concerning Genetic Testing for Health Purposes, have not been signed and ratified in Estonia. In the light of that, it is justified to say that the Oviedo Convention and its additional protocols have had direct impact on Estonian legal framework. The additional protocol concerning transplantation of organs and tissues of human origin was the bases for our Transplantation and Organ Tissues Act, adopted in 2002. The Penal Code was also amended in 2002, according to it human cloning is forbidden now (Article 130).

The convention and the ratified additional protocols have been translated into Estonian with the help of the Council of Europe. The documents have been also published in Estonian and the publication has been widely distributed among medical people.

To introduce the convention and its additional protocols, there have been papers published in local scientific medical journals; the issue has also been under discussion during postgraduate training courses on bioethics.

In order to systematically develop the activities of ethical review boards in Estonia, seminars for members of the ethics review boards take place regularly once a year. The cooperation with other Baltic countries has been es-

tablished also, and to implement bioethics into practice, clinical ethics committees have been established in two major hospitals in Estonia.

The 1990s were the period of rapid change and integration. Estonia took over many documents issued by the Council of Europe. At present, nearly all documents which could be integrated into the legal system, have been already integrated and therefore the role of the Council of Europe has diminished. The fact that from 2004 Estonia belongs to the EU probably plays an important role as well.

The two latest additional protocols, i.e. those concerning biomedical research and genetic testing for health purposes, have not been signed and ratified because it has not been considered to be a priority at the political level. There is no legal incompatibility with the Estonian legal framework, and the Estonian Council on Bioethics has made a proposal to the Minister of Social Affairs to start the signing and ratification process of the two additional protocols concerning biomedical research and genetic testing for health purposes. Signing and ratifying the additional protocol concerning biomedical research would be especially important, because the scientific research in Estonia should be regulated better. There are laws regulating clinical trials and research on human genes, but not other human subject research. Situation like this cannot be satisfactory and therefore the national council has started the process of signing and ratifying the additional protocol concerning biomedical research.

About the Author

Ms. Kristi Lõuk has a BA in philosophy from the Department of Philosophy of the University of Tartu, where she graduated in 2002. In the academic year 2004/2005 she studied in University of Konstanz, Germany. Currently she is finishing her MA studies in practical philosophy in the Department of Philosophy. Since January 2007 is Kristi a member of the Ethics Review Committee on Human Research of the University of Tartu and since March 2008 member and secretary of Estonian Bioethics Council. Kristi is working in the Centre for Ethics of the University of Tartu.

Correspondence to: Ms. Kristi Lõuk, Estonian Council on Bioethics, Centre for Ethics, University of Tartu, Ülikooli 18, 50090, Tartu, Estonia, e-mail: kristi.louk@ut.ee

IMPLEMENTATION BY THE REPUBLIC OF MOLDOVA OF THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE AND THE ADDITIONAL PROTOCOLS TO THE CONVENTION

Igor Codreanu

Center of Dialysis and Kidney Transplantation, Republican Clinical Hospital,Chisinau, Moldova

Founded in 1949, the Council of Europe is the oldest and largest of all European institutions and now numbers 47 member states. One of its founding principles is that of increasing co-operation between member states to improve the quality of life for all European citizens. Within this context of intergovernmental co-operation in the field of health, the Council of Europe has consistently selected ethical problems to study. Taking into account that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realization of human rights and fundamental freedoms, the Republic of Moldova decided to take in its internal laws the necessary measures to give effect to the provisions of the Oviedo Convention.

The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine concluded on 4th of April 1997at Oviedo (Asturias), was signed by the Republic of Moldova on 06th of May 1997. The Convention was ratified19th of July 2002 with the following statement: "In accordance with the article 35 of the Convention, The Republic of Moldova declares that until the reestablishment of the territorial integrity of the state, the stipulations of the Convention could be applied only in the territories controlled by the Government of the Republic of Moldova". The Convention entered into force in the Republic of Moldova on the 01st of March 2003.

Taking into consideration the necessity of better implementation of the Convention stipulations the Council of Europe decided to adopt the Additional Protocols, as follows:

The Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings was adopted by the Council of Europe and signed by the Republic of Moldova in Paris, on 12th of January 1998. The Additional Protocol was ratified by the Republic of Moldova on19th of July 2002 and entered into force in the Republic of Moldova on the 01st of March 2003. In the context of implementation of the mentioned Additional Protocol, art.144 of the Penal Code of the Republic of Moldova on Cloning which stipulates that human being creation by cloning is punished with prison as well as, point 6 art.9 of the law nr.185, dated 24.05.2001 of the Republic of Moldova on reproductive health care and family planning which stipulates that it is prohibited the use of sexual cells and embryos with the purpose of human being cloning, are in correspondence with its provisions.

The Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin was adopted by the Council of Europe at Strasburg on 24th of January 2002 and signed by the Republic of Moldova on 08th of February 2007. The Additional Protocol was ratified on 06th of December 2007. The Additional protocol entered into force in the Republic of Moldova on the 01st of June 2008.

Further to the ratification of the Additional Protocol and the request of the Republic of Moldova authorities, the Council of Europe Steering Committee on Bioethics (CDBI) in collaboration with the European Committee (Partial Agreement) on Organ Transplantation (CD-P-TO) organized on 03-04 of July 2008 in Chisinau a seminar on "Ethical and organizational aspects of organ transplantation" with the participation of Mr. Alexander VLADYCHENKO, Director General of Social Cohesion, Council of Europe and Dr Larisa CATRINICI, Minister of Health, Republic of Moldova. During the seminar the Council of Europe experts in collaboration with the local transplant professionals set up an action plan for the next 3 years to support the implementation of the stipulation of the Additional Protocol and newly adopted Transplant Law and set up the Transplant Agency in the Republic of Moldova. The Parliament of the Republic of Moldova adopted the law nr.42 dated March 6, 2008 on 'Transplantation of human organs, tissues and cells" according to the Additional Protocol recommendations and principles.

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes was adopted by the Council of Europe in Strasburg on 27th of November 2008 and signed by the permanent Representative of the Republic of Moldova to the Council of Europe on 11th of November 2008.

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research was adopted by the Council of Europe in Strasbourg on 25th of January 2005 and signed by the Republic of Moldova. National Committee of Ethics for clinical trials is in charge of information, referral, coordination, reporting and guidance of clinical trials and biomedical practice. National Committee of Ethics for clinical trials is set by the Ministry of Health. The „Regulation on National Committee of Ethics for clinical trials" was prepared in accordance with The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. In accordance with Article 14 of Law No. 263 of 27. 10. 2005. "The patients' rights and responsibilities" and the rules of Good Clinical Practice the decision of the National Committee of Ethics for clinical trials is binding. The Committee is established as an autonomous organization and is operating under a rule approved by the Government. In Moldova, the National Committee of Ethics for clinical trials is an independent authority, including members working in health area and those outside the mentioned area, whose responsibility is to protect the rights, safety and welfare of human subjects included in the trial, and to serve society as a guarantee of such protection, including the examination, approval of the study protocol, investigators applications, research centers (clinical bases), and the materials and methods for obtaining and documenting informed consent of the participants.

About the Author

Dr. Igor Codreanu, MD - graduated the Medical and Pharmacology University "N. Testemitanu" in Chisinau, Moldova in 1989. Upon graduation he did his internship on urology and since 1990 is working as urologist/transplantologist in the Center of dialysis and kidney transplantation, Republican Clinical Hospital, Chisinau, Moldova. Between 2003 and 2006 he made his Fellowship Training in Nephrology and Kidney Transplantation at the Mari Negri Institute of Pharmacological Research, Bergamo, Italy. Simultaneously, since 2005 he is the National Transplant Coordinator. For the last four years he is the Republic of Moldova expert at the Council of Europe Committee on Organ Transplantation (CD-P-TO), European Directorate for the Quality of Medicine and HealthCare, Directorate General of Social Cohesion.

Correspondence to: Dr. Igor Codreanu, MD, Centrul de Dializa si Transplant Renal, Spitalul Clinic Republican, str. N. Testemitanu, 29, MD-2025, Chisinau, Moldova
e-mail: renalfoundation@yahoo.com

ACTIVITIES CONCERNING SIGNING, RATIFICATION, IMPACT ON LEGISLATION AND PRACTICES OF THE OVIEDO CONVENTION AND ITS PROTOCOLS IN MONTENEGRO

Omer Adžović

Institut za bolesti djece, Podgorica, Montenegro

In the period until May 21st 2006, when Montenegro was in the state union with Serbia, Oviedo convention was signed. New Healthcare and Health insurance laws aligned with the latest of medical standards, including the standards of Oviedo convention, were adopted, which enabled the following legislation in the field of healthcare. In this period, the Law on protection of persons with mental disabilities was also adopted, in alignment with the Convention, its protocols and related CDBI documents.

After gaining independence on May 21st 2006, having a commitment towards an overall development and prosperity of our nation, including accession to the European Union, the new Constitution was ratified in the year of 2007, in accordance with the high democratic standards of Europe and developed world, which provided constitutional grounds for legislation aligned with the standards of EU.

Having in mind the importance of development of biology and medicine and possible ethical problems and dilemmas we could encounter in practice, Article 27 of the Constitution, which I will now read in its entirety, is concerned with the field of bioethics:

> ***Biomedicine***
>
> *The right of a person and dignity of a human being with regard to the application of biology and medicine shall be guaranteed.*
>
> *Any intervention aimed at creating a human being that is genetically identical to another human being living or dead shall be prohibited.*
>
> *It is prohibited to perform medical and other experiments on human beings, without their permission.*

This article gave the constitutional foundation for adoption of laws in the field of medicine, genetics and biology in general, in accordance with Oviedo convention and its protocols. Process of ratification of Oviedo convention is undergoing and it is expected it will be finalized sometime early next year. Laws adopted in this period include the Law on secure blood procurement for the medical purposes, which is in its entirety aligned with the relevant documents of the Council of Europe; also, the Law on medical records procedure has been adopted, the Law on abortion, etc.

Genetic procedures with the purpose of diagnostics, prevention and treatment are being conducted in Montenegro. Two private and one public medical facility conduct methods of medically assisted procreation, and that is why we worked hard in last year to prepare a draft law on assisted procreation. The bill is currently in legislative procedure, and its adoption now is a matter of days. Also, in procedure is the law on transplantation of human tissues and organs. This law is particularly important, since its adoption will for the first time thoroughly regulate this field of medical practice.

The plans for this year also include the making of the law on protection of genetic data, as well as the law on obtaining, safekeeping and use of biological material of human origin for health and research purposes.

This legislation helps general healthcare reform in Montenegro, which should ultimately help implementation of these laws. Healthcare reform has been conducted at the primary level, as the institution of the "chosen medical practitioner" has been established. The idea is that this chosen doctor provides primary healthcare for the persons that chose him. In the forthcoming period the reform of the secondary and tertiary sector are planned.

About the Author

Mr. Omer Adžović, MD – earned his medical doctor degree at University of Belgrade Medical School in 1967. He specialized in Pediatrics at the Institute for Pediatrics in Belgrade in 1978, earned his master degree in the field of Pulmonology in 1985. During his professional engagement, he devoted his career to the pediatric pulmonology, while working in several public facilities. He is the founder of the Department for Pulmonology within the Institute for Children's Diseases of the Clinical Centre of Montenegro. He works at the Institute since 1981. In the period from 2005 to 2008, he was the executive director of this prominent institution. Additionally, he served as a public official in several terms, including 4 terms in either Federal or State legislative bodies. He is the representative of Montenegro in the Steering Committee on Bioethics of Council of Europe.

Correspondence to: Mr. Omer Adžović, MD, Institute of Children's Diseases, Clinical Centre of Montenegro, Ljubljanska bb, 20000 Podgorica, Montenegro
e-mail: selmanadzovic@yahoo. com

RATIFICATION OF THE OVIEDO CONVENTION: WHAT ARE THE DIFFICULTIES?

Adam Fronczak

Ministry of Health, Warszawa, Poland

Ladies and Gentlemen,*

First of all let me congratulate the initiators and the hosts of this conference on their efforts to organise the meeting on the 10th anniversary of entry into force of *the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine known as the Convention on Human Rights and Biomedicine.* This is a unique opportunity to discuss the main obstacles for the Convention to be approved by these countries, which have so far had problems with application of the legal standards drafted in this document.

As you know *the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine* is today indisputably considered to be the most important European level regulation pertaining to bioethics. The work on the Convention lasted 6 years and was a result of a stormy public debate involving scientists, lawyers, ethicists and doctors. So much emotion was caused not only by very difficult problems of medical and ethical nature, which the creators of the Convention undertook to regulate, but also by the fact that the document was to be of legal nature, thus binding for the individual countries, despite the fact that it referred to a fragile consensus in the domains of science and ethics. It was the controversies related to theses provisions that resulted in the situation, where some of countries of the Council of Europe have not ratified or even signed the Convention to date. However, taking into account all disadvantages and advantages of the provisions of the Convention, one should consider reaching the international consensus on such sensitive matters a great success.

The Republic of Poland signed *the Oviedo Convention and the Additional Protocol on Prohibition of Cloning Human Beings* on 7 May 1999. The remaining three additional protocols have not been signed. Until today the Convention has not been ratified by Poland, primarily due to the lack of scientific and ethical consensus on its certain provisions. This does not mean however, that the Polish government does not undertake efforts to achieve such a consensus. In the light of the rapid progress of biomedical technologies and related increasing legal and ethical problems, the last years saw intensified efforts to adapt Polish legislation related to medicine to the provisions of the Oviedo Convention. The Group on Bioethical Convention attached to the President of the Council of Ministers established last year presented – sometimes alternative – recommendations pertaining to the conditions that have to be met while adapting the Polish law to the standards making it possible to ratify the Convention on Biomedicine.

I will now refer briefly to the most important areas regulated by the Convention and discuss them in the Polish context.

As regards the protection of **dignity and identity of human beings and the guarantee for all persons to have their integrity respected,** it should be stressed that the protection of inherent dignity of any human being is the basic principle in the preamble to the Constitution. Article 30 of the Constitution expresses „the inherent and inalienable human dignity", which is „the source of freedom and rights of human beings and citizens", acknowledging the sanctity of human dignity and putting an obligation on the public authorities to protect and respect it. The specific provisions of the Polish law lack the key definitions for notions of a person or a human being. This is not really a result of a deliberate decision of the law maker, but rather of an absence of regulations in the areas of genetics, medically assisted procreation, transplantation of foetal tissues or the boundaries of admissibility for scientific research on in vitro embryos, as well as a complete ban on treating the human body or its parts as a source of a material benefit. On the other hand there are no obstacles to provide full and identical protection to both human being and person. This is the direction in which the jurisprudence of the Supreme Court and of the Constitutional Tribunal goes.

In case of a conflict, **the interest and the welfare of the human being prevail** over the sole interest of science or society. This principle, formulated in Article 2 of the Convention applies primarily to scientific research. This provision in fact confirms the principle that scientific achievements and their most promising applications may not infringe human rights. On the axiological level the basic principle regulating the relationship between the freedom of scientific research and the basic human rights are regulated in the Constitution, which on one hand proclaims the freedom of scientific research, and on the other the dignity of all persons and respect for their freedom and privacy, as well as independence in taking decisions on participation in experimental research. The primacy of the human being is further confirmed in legal provisions pertaining to medical experiments on humans.

The equitable access to health care of appropriate quality is regulated by Article 68 of the Polish Constitution, pursuant to which all persons have the right to health care, while the public authorities provide the equitable access to health care services financed from public funds to all

citizens, irrespective of their material status. These provisions include the premise for respecting a certain level of quality of medical services, certain necessary „minimum quality", which facilitates realisation of this right, and below which one could suspect infringement of the constitutional guarantee. The implementation of this premise is also dependent on existence of a number of specific regulations. The existing legal system provides for a vast majority of such criteria. The relevant standards have been established as regards the qualifications of medical personnel, the premises and equipment of health care institutions. The relevant standards are established in the codes of professional ethics of doctors, nurses and midwives.

The principle of free and informed consent defines autonomy of patients and means that nobody can be forced to undergo any intervention without his or her consent. According to the modern idea of a relationship between a doctor and a patient, the condition for the legality of medical activities is the prior informed consent of a patient to medical intervention. The idea of consent consists of three separate, but equally important components. Firstly, the consent is only valid when the person who has given it has the capacity to perform acts in law. Secondly, the consent must be preceded by providing appropriate information as to the purpose and nature of the intervention as well as on its consequences. Thirdly, the consent must be given voluntarily. The notion of informed consent has been introduced to the Polish legal system through the *Act on health care institutions* providing that patients have the right *to give consent to specific health services or to deny them, having received relevant information*. The following expressions are of key importance here: *consent to specific health services* and *relevant information*. In other words the consent must be clear, refer to very specific treatment and be based on extensive and comprehensible information and explanations provided by a doctor. As regards high-risk interventions, the Polish law requires the consent to be given in writing. Pursuant to the relevant Act *a doctor may perform an operation or apply treatment or diagnostic method resulting in an increased risk for a patient after receiving his or her written consent.*

The Polish law does not have any detailed regulations in the field of **genetics**. The prohibition of discrimination based on genetic characteristics is contained in Article 21 of *the EU Charter of Fundamental Rights*. Apart from international documents binding for Poland, the general prohibition of discrimination based on any grounds in political, social and economic spheres is proclaimed by Article 32 of the Constitution. According to the Polish law the genetic interventions, including predictive tests, may be carried out in Poland without limitations. This includes out-of-health-domain interventions. The only exception is a prohibition on carrying out genetic tests or using its results for insurance purposes. In the light of the absence of other national regulations in the field of genetics and medically assisted procreation, the prohibition of performing genetic interventions for purposes other than health related and the prohibition of modifying reproductive cells intended for impregnation may not be directly applied in Poland. Further efforts in this field are thus necessary.

The basic principles referring to **experimental research on human beings** are contained in the Polish Constitution, which on one hand proclaims the freedom of scientific research and on the other freedom of all persons and the respect for autonomous decisions on participation in scientific experiments. Furthermore, Article 7 of the International Covenant on Civic and Political Rights binding to Poland prohibits any medical or scientific experiments without a voluntary consent of a participant. More detailed solutions are provided in the *Act on the profession of a physician*. Its regulations clearly point to admissibility of medical experiments (related to treatment or research) but with limitation resulting from the requirements to protect the rights of participating persons. Sometimes these provisions are not fully coherent.

So far the questions related to **in vitro fertilisation** have not been regulated in the Polish law. The only reference to this problem in legislation is made by exclusion of this health service from public financing. There is an ongoing debate in Poland on admissibility and principles for procreation assisted by this method. Varying and often mutually exclusive approaches to this problem can be found in this discussion – from a complete ban on in vitro fertilisation through introduction of legal limitations (more or less restrictive) for application of this procedure to providing the possibility of extensive application of this method with guarantees for financing these services from public funds. The assessment of this question is significantly influenced by the position of the Catholic Church, which unlike other Christian churches opposes this method of treating infertility. It should be stressed, that Article 53 of the Polish Constitution guarantees the freedom of conscience and religion to all citizens, and therefore this position cannot be conclusive.

As regards **the questions related to transplantations of cells, tissues and organs** it may be concluded, that the provisions of the *Bioethics Convention* and the Polish law are based on the same axiological system. Pursuant to *the Act of 1 July 2005 on collection, storage and transplantation of cells, tissues and organs*, cells, tissues and organs may be collected from a deceased person, if one did not express objection before death. In case of persons who do not have the full capacity to perform acts in law (for example minors) the objection may be expressed by their parents or guardians. Polish provisions require consent to be given each time by a living donor of cells, tissues and organs. Consent for giving this biological material by a living donor who is not related or married to the beneficiary must be granted by a court in the presence of specific personal reasons. Polish law expresses the principle that no payment or other benefit may be either demanded or accepted for cells, tissues and organs collected from a donor.

Ladies and Gentlemen,

The legal solutions I have presented are only a starting point in the process of adapting Polish legislation to the standards laid down by the *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine*. I do hope that soon the significant efforts undertaken by individual countries in order to regulate these extremely sensitive domains of science and medicine will bring satisfactory results. It is particularly important in the times of rapid technological progress in medical sciences, when the legal and ethical solutions lag behind these changes.

Thank you for your attention.

** Text of the speech given by Mr. A. Fronczak during the Working Session III of the conference.*

About the Author

Mr. Adam Fronczak, M.D. was born on 27.02.1957. In 1982 he graduated in medicine from Medical University of Łódź and specialized in internal diseases subsequently. In 1993 he defended his dissertation. In 2003 he specialized in clinical pharmacology and afterwards in public health. In the meantime he passed the exam for members of Supervisory Boards of State Treasury Companies. During 27 years of his professional career he wor-

ked in various medical, administrative and academic institutions (including Medical University in Łódź, various hospitals and Regional Office in Łódź) holding the high managerial positions (among others: Chancellor of the Medical University of Łódź, Director of the Maria Skłodowska-Curie Regional Specialist Hospital in Zgierz, Chair of the Regional Team for Medical Rescue Services). In 2007 he was nominated to the position of Undersecretary of State in the Ministry of Health. He is interested in tourism, history of art and cycling.

Correspondence to: Mr. Adam Fronczak, MD, Ministry of Health, ul. Miodowa 15, 00-952 Warsaw, Poland
e-mail: sekretariat-af@mz.gov.pl

THE IMPACT OF OVIEDO CONVENTION ON THE LEGISLATION AND PRACTICES IN ROMANIA

Cristina Gavrilovici

University of Medicine and Pharmacy Gr. T. Popa, Iasi, Romania

At this present moment Romania is a transitional country. From an ethical standpoint, this means that our society did not entirely define a set a values, but still "borrow" the western values, in our eagerness to catch up with all that we have lost during the half of the century of communism. Thus, Romania has very quickly adopted many EU directives and recommendations even when it was not EU country.

Romania has signed and ratified the Oviedo convention (OC), which became a Romanian law in 2001 (law no 17 regarding the ratification *of* Oviedo Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine and the first additional protocol regarding human cloning; the other three protocols are still pending). Ever since, the Oviedo Convention represented the "starting point" for many Romanian medical laws and a key reference for Romanian medical ethics. This is why we consider that OC has a great impact on Romanian legislations.

Almost every chapter of the OC represents a foundation for several Romanian Laws. Some general principles from the Chapter 1, such as the primacy of the human being have been introduced in the latest version of Romanian Civil Code (law of Romanian Civil Code, 17. 07. 2009) that particularly emphasize the respect of human beings and their rights, including the right to a good health and integrity (section 2 and 3 from the Civil Code).

Chapter 2 from OC, regarding the issue of "consent" is highlighted in Romanian deontology code (for physicians and nurses) (last revision 30.08.2008), in Law no 46/ 21.01.2003: Romanian patients' rights law and Law 487/2002: the law of mental health and protection of people with mental health.

Chapter 3 from OC, regarding the protection of private life and right to information is transformed into Law 677/12.12.2001 regarding the protection of persons in relation to personal data and the free circulation of these data and Law 584/29.10.2002 regarding the prevention of HIV/AIDS and protection of AIDS/HIV infected people (due to a large number of HIV infected children through horizontal transmission, Romania is one of the few countries that promulgated a law entirely designed to this disease and its social consequences).

Chapter 4, regarding the human genome did not produce a specific law on genetics. The only reference to this subject is related to the unacceptability of any eugenic practices, as it is stipulated in the Civil Code (in art 62-63 about potential intervention over the genetic traits). Romania did not ratify yet the additional protocol regarding genetic testing, but this is pending to promulgation.

Chapter 5 regarding the scientific research has produced the Law no 206/ 27.05.2004: Romanian research law and "The decision regarding the authorization of clinical trials (non-interventional)".

Chapter 6 regarding transplantation created the groundwork for Law 46: Romanian transplantation law.

As we can see, the impact for legislation is strong enough, and the good part is that many, if not all medical legislation in Romania has an ethical part or ethical impact.

However, the impact for practices is not as great. This is mainly because there is still a big gap between legislation and practice. Clinical ethics consultations are not a common practice in Romania, even if, officially there are bioethics committees in almost all hospitals. On the other hand, the functioning of research ethics committees is much better, all studies on human subjects or animals being scrutinized by this committee. Unfortunately not all Romanian research institutes have people trained in bioethics.

Regarding the implementation of transplantation law into practice, this has been the subject of hot debates, open to public as well. Our law is based on a clear opt-in system. However, regarding the cadaveric organ harvesting, article 7 from our transplantation law mentioned that physicians can proceed to organ removal from a dead body without family consent if no relative is found after the brain death has been declared. Since this article was considered as a slippery slope towards an 'opting out' system, the law has been retracted and now it is still pending.

In conclusion, we appreciate that it is easier to write a law than to implement a practice and we need programs to evaluate the implementation of ethical consultations and we need to further develop ethical teaching among persons who sit in ethical committees.

Oviedo Convention represents a launch for many ethical debates, and even if some disagreements still persist at the global international level, we need to move forward, not to reach consensus, but to respect diversity and look for harmonization as much as we can.

About the Author

Assoc. Prof. Cristina Gavrilovici, MD, PhD. is an associate professor in bioethics at the University of Medicine and Pharmacy "Gr. T. Popa", Iasi, Romania. She serves as the President of Research Ethics Committee of the same university and as a member of the Romanian Bioethics Committee. She holds MD and PhD degrees in medicine (pediatrics). She served as an expert in several ethical review panels within the EC's FP6 and FP7, and as a member of the Descartes Prize Grand Jury. She is co-editor of the Romanian Bioethics Journal. Dr. Gavrilovici has published so far three books and eleven book chapters in the fields of bioethics and medicine (pediatrics).

Correspondence to: Assoc. Prof. Cristina Gavrilovici, MD, PhD, Romanian Bioethics Committee, University of Medicine and Pharmacy Gr. T. Popa, Str. Ralet no 3, apt 7, Iasi, 700108, Romania, e-mail: cristina_gavrilovici@yahoo.com

BIOETHICS IN SERBIA AND THE OVIEDO CONVENTION AND ITS ADDITIONAL PROTOCOLS

Zvonko Magić, Hajrija Mujovic-Zornić, Dragoslav Marinković

National Committee for Bioethics of the UNESCO Commission of Serbia, Belgrade, Serbia

Introduction

Political and economical sanctions until 2001. After that economy had priority. Federal Government until 2006, till that moment all the time two governments (Federal and Republic): SFRY, Federal Republic of Yugoslavia, Serbia and Montenegro, Serbia (2006): Serbia successor of former Yugoslavia.

In October 2003, UNESCO Commission of Serbia and Montenegro established the National Committee for Bioethics, consisting of eleven members from Belgrade, Novi Sad, Nis and Podgorica. Four of them were members of the Serbian, one of the Montenegrin Academy of Sciences and Arts, and six of them are professors at the Faculties of Science, Medicine or Philosophy. Activities of the Committee include:

- application of the Declaration on Human Genetic Data with a survey of the situation in biomedical research in scientific and medical centres;
- active participation in preparations of the declaration on the universal norms in bioethics (UNESCO/Paris 2004-2005);
- participation in the initiative of UNESCO/ROSTE from Venice to conduct comparable tests in Serbia, Slovakia and Macedonia (as model-countries) on the levels of knowledge among medical practitioners about use of molecular biology and genetics in medicine;
- development of national legislation in the field of biomedical research.

The Committee is a member of the International Bioethics Committee (IBC) and of the Intergovernmental Bioethics Committee (IGBC) of UNESCO. At the 8th COMETH meeting in Dubrovnik (May 2005), we joined the thirty National Ethics Committees of the European Council, and accepted the Convention for the protection of human rights and dignity of the human being with regards to the application of biology and medicine (Oviedo, 1997), as well as its additional Protocols.

From the spring of the year 2006, due to the change of the status of our State, the Committee changed its name to the ***National Committee for Bioethics of UNESCO Commission of Serbia***. At present, it has 16 members, among them five academicians, eight university professors and three scientific counsellors, as representatives from different towns and fields of bio-medicine.

Activities of the National Committee for Bioethics

1. Bioethics in Science and Medicine. Under this title, the Committee organized a symposium with international participation at the Serbian Academy of Science and Arts in October 2006 – almost 200 participants were present. Program of the meeting included following topics: Declaration on genetic data, Convention on human rights and biomedicine, ethical aspects of investigation and use of genetically modified plants, ethical standards in scientific research, ethics of genetic counselling, public and physicians' awareness of genetic testing, bioethics at medical faculties and in health institutions in Serbia, ethical aspects of national bio-safety council issues, molecular biotechnology – ethical challenge of the 21st century, recommendations for legislation of genetic testing in science and medicine.

We applied to our Ministry of Health and Ministry of Science with suggestions that basic principles of bioethics have to be included into existing laws in these fields. One of the basic principles, ***that human cloning is prohibited in our country, is now clearly stated in our new Constitution of Republic of Serbia.***

2. Awareness of genetic testing in Serbia and Montenegro. Investigation was performed in Serbia and in Montenegro within the pilot program *Public and physician awareness of genetic testing in ethnically diverse populations (PPAGET project)* that was addressed to the lay public as potential users of gene tests and aimed to estimate general population willingness to participate in genetic testing; and to the general practitioners (GPs) to estimate knowledge concerning the availability and use of genetic testing and genetic counselling. Two different questionnaires were used: 1. for the lay public (19 questions – 865 questionnaires were collected) and 2. for the GPs (21 questions – 283 questionnaires were collected (participation from *Serbia & Montenegro, Slovakia, FYR Macedonia, Greece and Italy* under the supervision of *UNESCO-ROSTE* (Regional Bureau for Science in Europe).

Following conclusions were made from the data thus obtained: Physicians in the primary health care system are lacking basic knowledge about the medical genetics. There is no organized system for receiving the information on such topics. They are willing to refer their patients, but there is no adequate information about the protocols, referral system, insurance etc. Almost half did not give correct answer to specific questions, e.g. on how autosomal recessive diseases are inherited, or whether Down's syndrome is an inborn or an inherited disease. With increasing time interval from the graduation, the GPs' knowledge about medical genetics significantly decreases.

3. As a result of this project, UNESCO has accepted the next project entitled **GenEduNet** (Genetic Education Network) aimed to present basic knowledge from human genetics (experts from genetics) to the medical doctors in different countries from Europe, Africa and Asia. First meeting was held in July 2008 in Belgrade with 160 participants.

4. The Council of Europe Bioethical Instruments and Promotion of Research Ethics in Serbia. On June 28 – 29, 2007, a bilateral meeting of the specialists from the Bioethics Division of Health and Bioethics Department of the Council of Europe and the representatives of the National Committee for Bioethics of the UNESCO Commission for Serbia was held at the Serbian Academy of Sciences and Arts (bilateral meeting within the framework of the Cooperation Programme to Strengthen the Rule of Law - DEBRA). An overview of legal standards in the field of human rights and biomedicine in Europe has been presented by two members of the Steering Committee on Bioethics (CDBI), Professors Elmar Doppelfeld (Germany) and Jozef Glasa (Slovakia), as designated European experts. The overview of the state of implementation of the fundamental ethical principles in the Serbian law and institutions was given by the members of Serbian Bioethics Committee.

Following issues were dealt with within the meeting's program: activities of the Serbian Bioethics Committee, the work of the Council of Europe in the field of bioethics, additional protocol on biomedical research, re-

view of the main legal and ethical issues with regard to Serbian legislation, the UNESCO project of public and physicians' awareness on genetic testing in Serbia, ethics in research and science and activities of the national ethics committees. After meeting our Committee sent a written request to the Ministry of Foreign Affairs and to the Government of Serbia to ratify Oviedo Convention

Legislation

Nowadays, Serbia is in the situation to follow the example of developed countries, where the health care system is focused on the subjects of the system and on due standards of quality services. Essential and optimal care is in the function of the user, hence the patient's health and rights are the general purpose of the whole system. Having in mind that many European countries have acceded to the codification of patient's rights through multiple models (special law, charter, or under existing law), in this direction went also Serbian legislator by adopting several important acts in the field of health care. Although Serbia has a long tradition of health legislation, new laws are the first requirement for necessary reformatory changes, which need to be comprehensive and to take into account the needs in the area of health legislation. From a wider context, numerous issues have their basis in constitutionally guaranteed rights, penal law sanctions and civil law provisions.

The Constitution of Serbia (2006) guarantees fundamental rights and health protection through its known principles:

- Human life is untouchable (Article 24)
- Human dignity is untouchable and everyone shall be obliged to respect and protect it (Article 23)
- Physical and mental integrity is inviolable (Article 25)
- Nobody may be subjected to torture, inhuman or degrading treatment or punishment, nor subjected to medical and other experiments without their free consent (Article 25)
- Protection of personal data shall be guaranteed (Article 42)
- All are equal facing the Constitution and law (Article 21)
- Attained level of human and minority rights may not be reduced (Article 20)
- Everyone have the right to protection of their mental and physical health. (Article 68)
- Health care for children, pregnant women, mothers on maternity leave, single parents with children under seven years of age and elderly persons shall be provided from public budget unless it is provided in some other manner in accordance with the law; Health insurance; health care and establishing of health care funds shall be regulated by the law (Article 68)
- Everyone has the freedom to decide whether they shall procreate or not. The Republic of Serbia shall encourage parents to decide to have children and assist them in this matter (Article 63)
- The Constitution anticipates a new paragraph on the **prohibition of human cloning** within the Right to life provision (Article 24).

The Law on Health Care (2005) includes, for the first time, some of the basic patients' rights within a separate chapter and introduces the institution of a **Protector of patients' rights**. The Act anticipates the most important rights: self-determination, autonomy, inform consent, privacy, and the right to complain. A special provision refers to the patient undergoing a medical experiment (Article 38).

The law provides regulation of research on human beings. The main objectives of the regulation **are to establish a Central Ethics Committee of Serbia (end of 2007)** and local ethics committees (at the Clinical Centres and Hospitals).

Serbia has adopted new **codes of professional ethics in medicine** (2007) and **pharmacy** (2001), as well as guidelines for good medical practice of primary health care. However, there are still deficits in guidelines for other medical fields.

The Law on public Health, blood transfusion, cell, tissue and organ transplantation, and Assisted Medical Procreation (getting into force from January 1st 2010)

Conclusion

Regarding the specific laws in Serbia, the situation is still unsatisfactory. The multiple importance of medical law is still insufficiently understood. Way forward is not just in the simple decisions on the new laws in this area, but at the same time in the constant monitoring and re-shaping the national legislation that will follow the European and world trends in law. For instance, a law on patients' rights in Serbia would be an important step in the direction towards increased patient protection, or a specific law regulating the situation for mentally ill should be developed as soon as possible. Also, the patients' ombudsman should work in parallel with a complaint procedure.

At this point, there is a necessity of further harmonization of Serbian domestic legislation with European regulations that are indeed numerous in this area. In this perspective, it is also necessary for Serbia to join the European Convention on Human Rights and Biomedicine.

References

1. Magić Z., Radulović S., Branković-Magić M., Janković R., Marinković D., Dottorini S.: Awareness of Genetic Testing in Serbia & Montenegro. *Revista Romana de Bioetica,* 2006; 4: 82-88. **2.** Marinković D., Magić Z., Konstatinov K. (Eds.): *Bioethics in science and medicine*. Beograd: Unije bioloških društava Jugoslavije-Društvo genetičara Srbije; 2006. **3.** Marinković D, Magić Z, Konstatinov K, Mladenović-Drinić S. (Eds.): *Bilateral Meeting on Ethics in Biomedical Research*. Beograd: Unije bioloških društava Jugoslavije-Društvo genetičara Srbije; 2007.

About the Author

Dr. Zvonko Magić, MD, PhD. - born 10. 10. 1953, Knjazevac (Serbia). Specialist in Pathophysiology since 1984. Completed different courses from recombinant DNA technology. Professor of human genetics and medical ethics at the Medical School of Military Medical Academy (MMA) and other medical schools and faculty of natural sciences in Serbia. Mostly dealing with research and diagnostics in molecular oncology. Head of the Department for Clinical and Experimental Molecular Genetics. Secretary of the National Committee for Bioethics of Serbia & Montenegro (since 2003) and since 2009 Co-chairman of the National Committee for Bioethics of Serbia, member of the Ethics Committee of Ministry of Health, member of CDBI. Member of the editorial board of 3 professional journals, mentor of more than 20 doctorate students (PhDs).

Correspondence to: Prof. Zvonko Magić, Crnotravska 17, 11002 Belgrade, Serbia, e-mail: zvonkomag@yahoo.co.uk

COUNTRY REPORT – SLOVAK REPUBLIC

Jozef Glasa, Helena Glasová

Institute of Medical Ethics and Bioethics n. f.
Bratislava, Slovak Republic

The fall of totalitarian regimes in the countries of Central and Eastern Europe (CEE) in 1989/1990 paved the way to an unprecedented political, social, economical and cultural transition. For Slovakia, the Czech-Slovak 'Velvet Revolution' of November 1989 started these changes. Bioethics, discipline born anew or 'imported' from abroad, has frequently been invited to contribute toward the public debate beyond addressing the problems of medicine, health policies and legislation. Its agenda has been broadened to include the issues of family, social justice, environmental preservation and development, as well as the pressing challenges of ongoing cultural and moral change [1]. In Slovakia, bioethics was seen as an important ingredient and means of fostering the first serious health care reform attempt, prepared by the Slovak Ministry of Health in the years 1990-1992. This attitude of the Ministry created a fruitful atmosphere, in which the first years of life of the 'Slovakian bioethics' were supportive and welcoming – the institutions of bioethics were created and various activities, including bioethics education and publishing, were developed [2].

Soon after, the new representatives of the Slovakian institutions became to attend the international meetings and to work in various intergovernmental and international commissions, including those of the Council of Europe. This way Slovakia also started to take part in the regular work and other activities of the Council of Europe committees, including the present CDBI (Steering Committee on Bioethics). The interest and enthusiasm of some of those Slovakian representatives at CDBI was great enough to enable sufficient flow of information in a countrypetal way, allowing for the necessary learning processes and even enabling for some influence of the ideas and work of CDBI at the national scene. Interestingly enough, Slovakia was among the first countries to sign and ratify the Oviedo Convention and its first Additional Protocol.

Similarly to the other countries in the CEE region, the health care and biomedical research systems in Slovakia were in a great need of structural reform. It should have brought in an overall development and better quality, but also a moral/ethical renewal deemed necessary after more than 40-year period of the totalitarian 'real socialism'. Soon on, the need for an appropriate legislation support of the reform efforts became obvious. So as was the need for some guidance and professional support in the situation, when badly needed qualified professionals were still mostly recruited from the circles of 'the old guard'. Such 'totalitarian conservativism' allowed, sometimes, for almost bizarre interactions with the 'new people' returning from the quick and short study stays abroad... In this situation, the activities, and later on also the texts, including the legally binding Bioethics Convention of Oviedo and its Protocols, prepared by CoE structures, such as CDBI, became increasingly important.

In Slovakia, the first regional DEBRA 'International Bioethics Conference' took place in 1991 (it was devoted to the actual problems of medical ethics encountered in 4 participating CE countries – Slovakia, Czech Republic, Hungary and Poland). Later on further DEBRA conferences were held in Bratislava. Those were dealing with problems in medical ethics education in Europe (1993), family health and care (1995), health care under stress (1998), ethics committees in CEE countries (1999), ethics in human genetics (2001), and ethics support for medical practice (2004).

An important promoter of bioethics development in Slovakia in its early years was the Central Ethics Commit-tee at the Ministry of Health ('national' EC; founded 1990). Later on, the activities of the Chair of Medical Ethics (1991) and still later on (1992) those of the Institute of Medical Ethics and Bioethics (since 1994 – foundation; since 2004 – non-investment fund (n. f.)) became more prominent, especially in education and research realms, as well as in the international networking and collaboration.

The biomedical and health care legislations were substantially changed 3 times in the 'post-November' Slovakia (in 1992, 1997 and in 2004), besides the relatively minor changes introduced within the process of legislation amendment. Though several legislation amendments allowed introduction, or improvements of the legal language inspired by the said CoE bioethics/bio-law instruments, the most profound legislation change took place in 2004. Then, a set of health care laws was prepared by the Ministry of Health and adopted by the Slovak Parliament. The preparation process of the new laws was difficult and prolonged. It had to take into account in the first place the legislative requirements of the accession process of Slovakia to EU. An active role in preparation and commenting on the new health legislation had the Central Ethics Committee of the Ministry of Health. This way, the drafting process of the legislation had been informed by the provisions contained in the relevant international bioethics instruments, among those, in the first place, by the Oviedo Convention and its Additional Protocols that were already available, or in an advanced stage of the preparation.

Among the laws then adopted, the most important was the Law No. 576/2004 Coll. on health care (later on many times amended, but still valid). The law should be regarded as the most important and comprehensive health care and biomedical legal text in Slovakia, the other health care laws, adopted together with it, deal with some more specific areas (e.g. health care providers, health insurance, etc.).

The law provides for the comprehensive legal framework in which health care is provided, including conducting of the biomedical research. The provisions contained in the law were kept in full accordance with the Oviedo Convention and its Protocols (the Slovak le-gislation system provides that the Convention and its Protocols take precedence over any of the Slovak laws that might be in contradiction to it). The problems cove-red by the law 576/2004 include e.g. patients' rights, ba-sic duties of the health care professionals, system of the health care provision, biomedical research, informed con-sent, ethics committees, transplantation, sterilization, etc.

The impact of the Oviedo Convention and its Protocols upon the development and improvement of good practices in Slovakia is difficult to assess exactly. No validated studies were performed to this effect so far. However, due to the comprehensive national legislation backing and quite developed education system for health care professionals in Slovakia (compulsory and state guaranteed), it can be said that the provisions of Oviedo Convention – via the precepts of the national legislation and other instruments – have been observed by the health care professionals in an increasing manner and thus influenced positively the developments in this sector. A study on details and processes of these developments might be interesting to perform. Till the time the results of such study are available, our conclusions are no more than 'an informed guess'.

References

1. Glasa, J.: Bioethics and challenges of a society in transition: The birth and development of bioethics in post – totalitarian Slovakia. Kennedy Institute of Ethics Journal, 10, 2000, No. 2, p. 165 – 170.
2. Glasa, J., Bielik, J., Ďačok, J., Glasová, M., Porubský, J.: Ethics committees (HECs/IRBs) and health care reform in the Slovak Republic: 1990 – 2000. HEC Forum, 12, 2000, No. 4, p. 358 – 366.

About the Author

Assoc. Prof. Jozef Glasa, M.D., PhD., PhD. – see p. 32.

Dr. Helena Glasová, MD, PhD. is a clinical pharmacologist, now based in London (UK), and co-founder of the Institute of Medical Ethics and Bioethics n. f.

OVERVIEW OF THE COUNTRY REPORTS PRESENTED AND THE CONFERENCE CONCLUSIONS

Jozef Glasa

Institute of Medical Ethics and Bioethics n. f.
Bratislava, Slovak Republic

Introduction

Delegates from 13 CEE countries took part in the International Bioethics Conference – *Oviedo Convention in Central and Eastern European Countries*, which was held in Bratislava (Slovakia) on September 24 – 25, 2009 (details at www.bioethics.sk). The meeting was prepared by the Secretariat of the Steering Committee on Bioethics (CDBI) of the Council of Europe (CoE), in collaboration with the Slovak Ministry of Health, Slovak Medical Association and the Institute of Medical Ethics and Bioethics n. f. in Bratislava as a regional international conference under the CoE's Program DEBRA.

The delegates were considering the characteristic traits of the situation and major challenges these countries face with regard to the area of biomedicine and health care and to the striking transition processes in these sectors and in general. Furthermore, they were looking into possible contributions and impact Oviedo Convention and its Additional Protocols may have had on the development of a novel biomedical and health care legislation, as well as on the promotion and observance of the good practices in their respective countries. Moreover, in preparation for the conference, Secretariat of CDBI undertook a special questionnaire survey on the relevant situations present in the CEE countries. The delegates were also looking into the possible ways forward in the processes of ratification and implementation of the Convention and its Protocols in their respective countries.

Situation in CEE Countries

In reporting and considering their respective countries' situations, the delegates noted that there were both striking differences and similarities/common traits present. Importance of a country non/membership in the European Union was also pointed out (it provides for many of the said differences – economical, social, cultural, and political). The similarities and differences were observed also with regard to the signing/ratification processes of the Convention and its Protocols in CEE countries. Most of the countries experienced, or are still experiencing complex transitions with regard to their political, economical and cultural lives. The transition is present in the countries in its various phases (early, medium, late, 'soon after'). It may also work in different phases in different sectors of a particular country. Those transitions were (and still may be) marked by unprecedented changes (social, cultural, economical, moral) that include/d also serious attempts in bringing about successful health care reforms (with varying degree of success/failure). There was (and still is) a strong need to introduce, develop, or improve the good practices, as well as the perceived necessity of a legal support of the reforms – past and ongoing. It is seen as a pressing necessity in re/drafting the various national legislations, and also to re/develop the national 'soft law' documents (guidelines, recommendations, codes of practice, standard procedures, etc.).

In struggling with the enormous demands posed by the novelty of processes and tasks of their complex transition efforts, the CEE countries were offered and provided with a lot of professional/expert help. It was coming from various international sources (e.g. European Commission, Council of Europe, World Health Organization, World Medical Association, various international organizations, university centres – European and overseas (USA), and international NGOs). In this, the legal expertise help provided by the existence and subsequent development of the Oviedo Convention and its Additional Protocols was of a special importance.

Contribution of the Oviedo Convention and its Additional Protocols

The delegates noted that the Oviedo Convention and its Protocols had been an important resource in re/drafting their own national health care and biomedical legislation. This resource should be seen not only in the texts of the Convention and its Protocols, but equally important have been the texts of Explanatory memoranda, recommendations, working and "white" papers, reviews, invited papers, survey results and other materials prepared by CDBI and its Secretariat. The regular and sometimes personal continuous participation of the country representatives in CDBI (CAHBI) work, especially in deliberations and consultations during the preparatory processes of CDBI materials and documents was pint pointed as a very useful education and information opportunity.

The value of various activities (especially bilateral and multilateral seminars and conferences) organised within the CoE's DEBRA Program was particularly emphasised. It was also noted that several countries that had originally benefitted from the DEBRA Program activities were able, later on, take part in DEBRA activities in other CoE member states.

The information and principles of the legal solutions contained in the Convention, its Protocols, in recommendations and various other materials prepared by CDBI, its Secretariat and Working Parties have been used by the CEE states in several modes, e.g. by: a) taking up the formulations of the principles contained in the Convention/Protocols and their re/formulation into the country's own legal language, b) taking portions of the texts translated (almost unchanged) into the new national legislation, c) using as a help in defining novel legal notions/terms.

Interestingly, the existence of a feed back mechanism was pointed out by some delegates: the CEE countries' delegations contributions to CDBI (CAHBI) debates, including the presentations of the countries' legal solu-

tions, influencing the CDBI debates on the newly prepared texts.

The delegates identified as the most important issues, i.e. those, where the Convention and its Protocols contribution was probably most substantive the following items: protection of human dignity, human rights – rights of the patient, informed consent, protection of persons not able to consent, ethics of biomedical research, transplantation, genetics – genetic tests for health purposes. They also pin-pointed some important issues still missing in, or dealt with insufficiently by the existing Convention and its Protocols texts (especially at the legally binding level): protection of the embryo, assisted reproduction, end-of-life decisions, mental health, and also long list of the newest or 'emerging issues' (e.g. nano-medicine, regenerative medicine, IT implants, human enhancement, etc.).

CEE Countries' Needs

The delegates discussed also the more-less specific needs of CEE countries in the area of biomedical and health care legislation and good practices development and implementation. The need to catch up with 'the delays' in their respective legislation developments and filling in the gaps in drafting the legislation still missing was underlined. Here, the Convention and its Protocols texts, as well as the information in the explanatory memoranda and preparatory materials and information may be especially helpful. Several delegates stressed the urgency to develop the national legislations (legislation and/or the 'soft law') on the newer or 'emerging' issues in biomedicine and health care (see above).

The successful implementation of the existing biomedical and health legislation in practice (i.e. developing and implementing of the good practices, standard procedures, 'know how', 'producing' well educated professionals, education of public – 'professional' and general, education of journalists, media, politicians, etc.) was seen as an equally important and pressing need (in several countries the problems in this respect were pointed out: "...the existing legislation does not work...").

In increasing the effectiveness of the national development processes, sharing of the national experiences and previously elaborated solutions (ethical/legal) was identified as another strong need. Several possibilities for the CEE countries to work together were pin-pointed (e.g. various forms of networking; development and sharing of the databases of the relevant 'know how' and information; meetings of experts/professionals; exchange of students (including doctoral – postgraduate) and professionals, etc.).

Suggestions for the Future CDBI Work

In conclusion of their deliberations the countries' delegations tried to identify and formulate some suggestions for future work of the Council of Europe – in particular of the Steering Committee on Bioethics – in the biomedical and health area. In this respect, continuation of the standard setting work of CDBI – especially on the 'missing issues' and 'newer/newest issues' – was strongly advocated. Also CDBI continuation in the guidance producing activities to enhance the implementation of already existing legal texts and recommendations was supported (such as e.g. the CoE's Guide for Research Ethics Committees). Further support for DEBRA program or for similar CoE supported (and funded) regular activities was seen as necessary (possible room for improvements was indicated).

Delegates also advocated the need for a concrete support of information activities aimed both at the professionals, politicians, and at the general public – development of novel approaches and use of contemporary and emerging information technologies was strongly recommended. The already conducted collection of relevant documentation and information in the field was applauded, but the need for further improvements was also articulated – including the need of providing for the necessary logistical and institutional support. This may possibly be done more effectively by developing and increasing collaboration with other partners in the field, to avoid duplicities and waste of precious resources (e.g. CoE and EU collaboration within dedicated FP projects).

The idea of providing a better institutional support for the research on bioethical/bio-law issues, especially with participation of young investigators and with enhanced possibilities for them to work at CoE and/or EU institutions and at the leading European academic and research institutions was supported by all delegations. The need for better and increased abilities and opportunities of working together/networking at the bilateral/multilateral, regional levels, EU and CoE and Global level was understood as basic pre-requisite for future work and development.

The most important common goal in this area, i.e. in the biomedical ethics and bio-law, should be the development of a possible 'common European ethical space /area', enabling all European countries to face the 'upcoming new' and 'persisting old' ethical challenges in the biomedicine and health care sectors together.

About the Author

Assoc. Prof. Jozef Glasa, M.D., PhD., PhD. – physician and clinical researcher, teaches clinical pharmacology, therapeutics, hepatology and bioethics at the Slovak Medical University (SMU), Bratislava. Deputy head, Institute of Pharmacology and Clinical Pharmacology SMU; director, Institute of Medical Ethics and Bioethics n. f.; editor, *Medical Ethics & Bioethics*; past chairman, member, Ethics Committee, Ministry of Health, Slovak Republic (SR); president, Slovak Society of Clinical Pharmacology; scientific secretary, Slovak Society of Hepatology; member, Council of Europe Steering Committee on Bioethics (CDBI), past Bureau member of CDBI and of COMETH; member, European Group on Ethics in Science and New Technologies (EGE); Board member of the European Forum of Good Clinical Practice (EF GCP).

Correspondence to: Assoc. Prof. Jozef Glasa, MD, PhD., PhD., Institute of Medical Ethics and Bioethics n. f., Vysoká 32, 81106 Bratislava, Slovak Republic, e-mail: jozef.glasa@szu.sk

ISSN 1335-0560

Included into Medline ™ and Bibliographia medica slovaca
Web: www.bioetika.sk, www. bioethics.sk

PRINTED IN SLOVAKIA