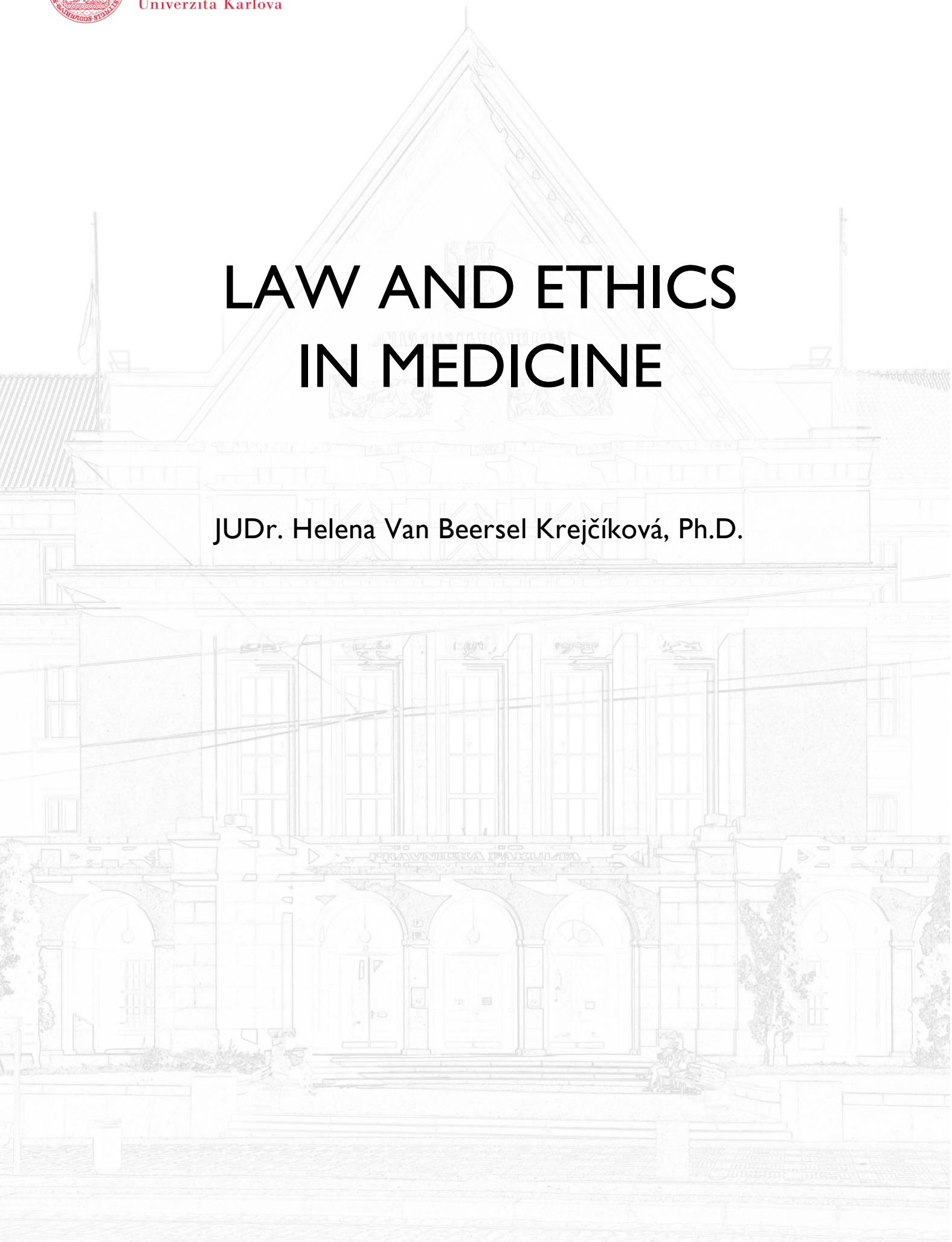




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# LAW AND ETHICS IN MEDICINE

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# INTRODUCTION

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**Dear participants of the course Law and Ethics in Medicine,**

Welcome to the course Law and Ethics in Medicine!

Please allow me to briefly introduce the nature and goals of this course. As you will realise already by having the very first look at this Reading Material, the Reading Material is not meant to be a textbook, nor is the course supposed to consist of lectures. The main idea is that we will work together in an interactive way, so you can gain theoretical knowledge through dealing with relevant case law, selected legal provisions, real life case studies, newspaper articles etc. In addition, the course will also target your ability to conduct a critical analysis, together with the ability to reason for and communicate your opinion and to have a challenging discussion regarding highly controversial issues.

As the name of the course implies, our discussion will not be restricted exclusively to the legal aspects of providing healthcare. You will be prepared to solve a case whilst switching your perspective from national law to foreign law and to medical ethics and to understand the different positions and possible differences in the conclusions.

Looking forward to meeting you all soon!

Helena Van Beersel Krejčíková



# I. LEGAL ASPECTS OF HEALTHCARE PROVIDED IN THE CZECH REPUBLIC

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In order to discuss hard medico-legal and bioethical<sup>1</sup> cases, one needs to know the relevant legal regulation and its limitations, i.e. to understand that sometimes what is legal is not necessarily also ethical. Indeed, a legal duty may differ from what a healthcare worker feels is the right thing to do, and a good medical lawyer should be aware of possible conflicts of legal and ethical duties on the side of a healthcare worker.

During this session, we are going to focus on the basis of Czech medical law<sup>2</sup>. Czech medical law, which is heavily influenced by European law, is unfortunately extremely fragmented. For the purposes of this course, it is crucial to have knowledge of the legal position of a patient, healthcare worker, healthcare provider, and next of kin of the patient, including their mutual rights and duties. These could be partially found in selected provisions of the Health Services Act (Act on Healthcare Services) that are going to be analysed.

A real case study (Case of a polymorbid patient) is going to be discussed from the point of view of Czech medical law,

in order to

- 1) explain the legal terms used in the Act on Healthcare Services;
- 2) define the legal duties of a doctor and to challenge the extent of legal certainty Czech medical law provides a healthcare worker with.

## 1. PROTECTION OF FUNDAMENTAL HUMAN RIGHTS OF THE PATIENT FROM THE EUROPEAN PERSPECTIVE

### 1. THE ROLE OF COUNCIL OF EUROPE

By drafting the Convention for the Protection of Human Rights and Fundamental Freedoms (referred further as Convention) in 1950, the leading role of Council of Europe on the field of fundamental human rights was acknowledged. Even though the Convention is not meant to provide a specific patient's rights, especially the provisions on right to life, prohibition of torture (including the prohibition of inhuman or degrading treatment), right to liberty and right to respect for private and family life have been crucial in famous cases such as *Pretty v. UK*, *Glass v. UK*, *Evans v. UK*, *Vo v. France*, *Mauriece v. France*, *Armoniene and Biriuk v. Lithuania*, *A., B. and C. v. Ireland* etc. brought before European Court of Human Rights (ECHR) actually by patients.<sup>3</sup> The influence of case law of European Court of Human Rights as well as the influence of Convention on some features of domestic medical law therefore is conceivable. By consistent focus on human rights in domestic law there is in fact some kind of coordination element provided by the ECHR.

However, despite the international machinery observing and enforcing engagements undertaken by the Parties in order to secure rights and freedoms set down by the

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<sup>1</sup> The term *bioethics* is to be interchangeably with *medical ethics*.

<sup>2</sup> The term *medical law* is to be used interchangeably with *health law*.

<sup>3</sup> See more case law on

[https://www.coe.int/t/dg3/healthbioethic/texts\\_and\\_documents/Bioethics\\_and\\_caselaw\\_Court\\_EN.pdf](https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Bioethics_and_caselaw_Court_EN.pdf). The document is also available on Moodle.

Convention and almost a contrario to what was indicated above, it is often the respect for already existing national law which seems to be significant. For illustration, it was brightly explained in *Pretty v. UK* that the right to life declared by Article 2 arches over many approaches to the protection of life – one extreme is Poland, where abortion is, because of the protection of a fetus' life, strictly regarded as a criminal offence unless the life of the woman is endangered; the other extreme is Netherlands, Belgium, Luxemburg and Spain where active euthanasia (i.e. life termination on request) is decriminalised.

### **1.1.1 EUROPEAN SOCIAL CHARTER**

The European Social Charter, the counterpart of the European Convention on Human Rights in the sphere of economic and social rights, was introduced by Council of Europe in 1961. Among all rights guaranteed by the Charter, including in Part II the right to work, the right to organise, the right to bargain collectively, the right to social security, the right to social and medical assistance, the right to the social, legal and economic protection of the family, and the right to protection and assistance for migrant workers and their families, there is the right to protection of health recognised by Article 11: "With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co operation with public or private organisations, to take appropriate measures designed inter alia:

1. to remove as far as possible the causes of ill health;
2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;
3. to prevent as far as possible epidemic, endemic and other diseases. "

The rules set up for ratification of the European Social Charter require any State that ratifies the Charter to undertake the obligation of at least 5 of Articles 1, 5, 6, 12, 13, 16 and 19, and such a number of Articles or numbered paragraphs that the total number of Articles or paragraphs is not less than 10 Articles or 45 numbered paragraphs of Part II of the Charter. If only the demanded minimum were to be chosen by the Parties, the final effect of the document as a whole would probably not be great. However, because of the fact that the Parties consider themselves often to be bound more extensively than the requirement for successful ratification has ordered, the impact of the international framework of the European Social Charter should not be underestimated.

### **1.1.2 TREATIES OF COUNCIL OF EUROPE RELATING TO BIOMEDICINE**

Since its foundation, Council of Europe has introduced an impressive amount of legally binding documents on human rights, including treaties with focus on subject-matters such as public law and biomedicine. Among them all, the Convention on Human Rights and Biomedicine is considered as the authority of highest importance with regards to medical law.

Convention on Human Rights and Biomedicine (Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine) came into effect on 1.12. 1999 and since its opening to signature it has been ratified by 29 Member States. Beside these, another 6 members of Council of Europe - namely Italy, Ukraine, Luxembourg, The Netherlands, Poland and Sweden - signed the treaty without subsequent domestic action (ratification), i.e. they are not subject to its

effect from the perspective of international law. 3 out of the 29 members who underwent the procedure of ratification expressed at least one reservation to the treaty. However, because of article 1 of Section 2 of the Convention ("each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention") there is a unifying consequence of the Convention on Human Rights and Biomedicine concerning the issue of informed consent, right to information about one's own health, the removal of organs and other tissues for the purpose of transplantation, medical research etc., at least to the extent that it provides a minimal standard of protection.

## **1.2 LINK BETWEEN COUNCIL OF EUROPE AND THE EU**

Although the Court of Justice (of the EU) should not be understood as a European human rights court, human rights doctrine has not been entirely absent in EC/EU law, as the requirement of protection of fundamental human rights and freedoms has been referred to inter alia as a part of the basic principles which should be followed by the applicant states during the accession procedure. These fundamental principles used to be enumerated in former Art. 6 (1) EU Treaty (Art. 6 (1) Maastricht Treaty as amended by Treaty of Amsterdam and Treaty of Nice) and used to consist of the principle of liberty, democracy, respect of human rights and fundamental freedoms, and the Rule of Law, which are common to the Member States.

As far as the respect of human rights is concerned, although the ratification of the European Convention for the Protection of Human Rights and Fundamental Freedoms has never been an explicit obligation for membership of the Council of Europe, it is also mentioned as a de facto condition for EU membership.

The consolidated Article 6 EU Treaty (as amended by Lisbon Treaty) in its Para 2 and 3 expressly defines the relationship between protection of human rights provided by Council of Europe and that provided by the EU as follows: "The Union shall accede to the European Convention for the Protection of Human Rights and Fundamental Freedoms. Such accession shall not affect the Union's competences as defined in the Treaties. Fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union's law."

In 1999 the European Council launched an initiative to draft a Charter of Fundamental Rights for the EU, as a result of discussion on whether the EU should accede to the ECHR or should have its own Bill of Rights. Finally as could be found in Article 6 Para 1 Treaty on the EU, the Lisbon Treaty made the Charter of Fundamental Rights legally binding on Member States with the limitation that "the provisions of the Charter shall not extend in any way the competences of the Union as defined in the Treaties. "

According to Article 35 of Charter of Fundamental Rights of the European Union, which is entitled as Health Care, "everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices." In addition, "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities." In other words, albeit the right to preventive health care and to medical treatment is from now on established as one of the fundamental rights of EU citizens, it only is to be recognised under the conditions defined by national law, which is why this provision in fact should be



interpreted rather cautiously, in letter and spirit, regarding its eventual harmonising consequences.<sup>4</sup>

### 1.3 TASKS REGARDING THE PROTECTION OF FUNDAMENTAL RIGHTS

- A. What is meant by European (medical) law?
- B. To what extent does European law influence the rights of a patient residing in an EU country? Give some examples.

## 2. CASE OF A POLYMORBID PATIENT

An ambulance was called to an 89 year-old polymorbid patient with a wrist fracture. The patient had been suffering from serious cardiac disease, breast cancer, renal insufficiency, incontinence and early stage of dementia. The attending doctor examined the patient in private and came to the conclusion that she was in a terminal stage of her diseases. She asked the doctor not to tell her daughters, because she wanted to protect them from the tragic news. After the doctor finished the examination, he was approached by the younger daughter of the patient, who was the primary carer and had been living with the patient for years. The daughter told the doctor that she knew her mum was dying, but was begging the doctor not to tell the patient, as it might stress the patient unnecessarily. The daughter strongly believed that the best thing for her mum would be to enjoy her last days or weeks peacefully at home. During the conversation between the younger daughter and the doctor there was a phone call. It was the older daughter of the patient, very much demanding a hospitalisation of the patient and as intensive care as possible.

### 2.1 TASKS REGARDING THE CASE:

- A. What is your understanding of all the terms (in italics) used in the text?
- B. The underlined phrases in the text refer to legal institutes from the Act on Healthcare Services. Could you identify them (see below the selected provisions of the Act)?
- C. Regardless of what the law says, what would you do if you were the doctor?  
Would you provide the daughter(s) with the information about diagnosis etc.?  
Would you take the patient to the hospital?  
Explain.
- D. What is/are the legal problem(s) here which the doctor has to face?
- E. Is there any other information that would be relevant in resolving this case?

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<sup>4</sup> Based on the paper PETERKOVÁ, Helena et al. The Phenomenon of Harmonisation in European Medical Law. *Medicine and Law*, roč. 31, 2012, č. 1. s. 1-17.

### 3. HEALTH SERVICES ACT

#### Act No. 372/2011 Coll., on health services and on conditions of their provision (the Health Services Act)<sup>5</sup>:

...

##### Section 28

(1) Health services may be provided to the patient only with his/her free and informed consent, unless otherwise provided in this Act.

(2) The patient shall be entitled to the provision of health services at the appropriate professional level.

(3) Whilst being provided with health services, the patient is also entitled

(a) to respect, to being treated with dignity, to courtesy and respect for privacy whilst being provided with health services, in accordance with the nature of health services,

(b) to choose a provider of health services, who is authorised to provide health services that meet the patient's health needs, and a health facility, unless otherwise provided in this Act or in other legislation,

(c) to request consultancy services from a different provider or a healthcare professional than the current ones; this shall not apply in the case of urgent care or in the case of custody, imprisonment or detention,

d) to be acquainted with the internal rules of the inpatient or one-day care healthcare facility (hereinafter referred to as the "Internal Rules"),

e) to

1. the continuous presence of a legal guardian or a person appointed by a legal guardian, a foster parent or another person to whom the patient has been entrusted, by decision of the court or of another body, if the patient is a minor,

2. the continuous presence of a caregiver or a person appointed by a caregiver, if the patient is a person whose legal capacity is limited so that s/he is not competent to assess the provision of health services, or the consequences of their provision (hereinafter referred to as "a patient with a limited legal capacity"),

3. the presence of a next of kin<sup>6</sup> or a person designated by the patient,

in accordance with other legislation and internal rules, and provided that the presence of such persons does not impair the provision of health services; this shall not apply to persons in custody, imprisonment or security detention; this provision, however, does not affect S. 47 (2) b) of this Act.

...

##### Section 31

(1) The provider is obliged to

(a) ensure that the patient is adequately informed of his or her health condition and of the proposed individual treatment process and any changes thereto (hereinafter referred to as "health information") in a clear and comprehensible manner,

(b) enable the patient or a person designated by the patient to ask additional questions related to his/her health condition and proposed health services, which must be clearly answered.

(2) The health information referred to in Paragraph 1 comprises data on

(a) the cause and origin of the disease, if known, its stage and foreseeable development,

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<sup>5</sup> Available in June 2020 on: [http://www.mzcr.cz/Cizinci/dokumenty/act-no372/2011-collon-health-services-and-on-conditions-of-their-provision-18562\\_4129\\_23.html](http://www.mzcr.cz/Cizinci/dokumenty/act-no372/2011-collon-health-services-and-on-conditions-of-their-provision-18562_4129_23.html). Further also referred to as the Act on Health(care) Services.

<sup>6</sup> Originally: "close relative".

- (b) the purpose, nature, expected benefits, possible consequences and risks of the proposed health services, including individual medical procedures,
  - (c) other options for the provision of health services, their suitability, benefits and risks to the patient,
  - (d) other necessary treatment,
  - (e) limitations and recommendations on lifestyle with regard to his/her health condition and
  - f) the possibility
1. to waive the provision of health information pursuant to S. 32 and
  2. to designate persons pursuant to S. 32 and 33 or to issue a ban on health information pursuant to S. 33.

Health information is communicated to the patient when admitted to care and then always whenever it is expedient to do so with regard to the health services provided or the patient's health condition.

...

### Section 32

(1) The patient may waive the right to the provision of information on his or her medical condition, or determine to whom it is to be provided. A record of waiving his/her right to the provision of health information and determining the person to whom health information shall be provided constitutes a part of the patient's medical record; the record shall be signed by the patient and the healthcare professional. A waiver of health information is disregarded if it is information that the patient is suffering from an infectious disease or from other illness in relation to which he or she may endanger the health or the lives of others.

(2) Information on the unfavorable diagnosis or prognosis of the patient's health condition may be withheld to the necessary extent and for the period necessary, if it can be reasonably assumed that its provision to the patient could cause serious harm to the patient.<sup>7</sup> It is not possible to proceed in accordance with the first sentence, if

- a) the information on a specific disease or predisposition to it represents the only way to enable the patient to take precautionary measures or to undergo early treatment,
- b) the patient's health poses a risk to his/her surroundings,
- c) the patient specifically asks for accurate and truthful information to be able to arrange for personal matters.

...

### 3.1 TASKS REGARDING THE ACT

A. Try to define the highlighted terms (in *italics*).

B. Is there a difference between a close relative and a next of kin? Which better corresponds to the Czech term "osoba blízká"? Explain.

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<sup>7</sup> What is known as "*therapeutical privilege*".

## 2. FUNDAMENTAL PRINCIPLES OF MEDICAL ETHICS

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There are many codes of ethics relevant for healthcare professionals, incl. first and foremost the Hippocratic Oath. It is questionable, though, to what extent they are universal, as they are, of course, territorial and they have been evolving over time. Even the general bioethical principles, as introduced by Childress and Beauchamp,<sup>8</sup> which might be understood as a source for the codes of ethics, seem to be valid merely in what are known as western countries.

However, in compliance with the old saying that law should be the moral minimum, it is important that there is a moral content in legal provisions, as opposed to medical law just consisting of technical norms. In other words, medical law should – at least to some extent - serve the same purpose as bioethics, i.e. define what is right (acceptable) and what is wrong (unacceptable). Unfortunately, medical law and bioethics do not always come to the same conclusion.

During this session, we are going to learn more about the two most relevant codes of ethics doctors are subject to. It is not rare that a disappointed patient blames a doctor for behaviour against the Hippocratic Oath, as if it was the most grievous failure possible. Based on how the Czech legal framework is established, we are going to decide to what extent the codes of ethics and/or the ethical norms they consist of are actually binding upon doctors. With that knowledge we are going to discuss the Case of the polymorbid patient again, this time from the ethical point of view. Last but not least, we are going to face yet a more complicated scenario in the Case of a 5 year-old dying patient.

### 1. CODE OF ETHICS OF THE CZECH MEDICAL CHAMBER

(professional order No. 10)

...

#### **§2 The physician and the performance of the profession**

(1) The physician will freely select and carry out within the framework of the physician's qualifications and competence those preventative, diagnostic and curative steps, which correspond to the current state of medical science and which the physician considers to be the most suitable for the patient. While doing so, the physician is obliged to respect to as great an extent as possible the will of the patient (or the patient's legal guardian).

(2) Every physician is obliged to provide immediate medical assistance in cases of endangered life or a direct serious threat to health.

(3) A physician must carry out his or her responsibilities in situations of public threat and during catastrophes of a natural or other nature.

(4) A physician is entitled to refuse to care for a patient for specialist reasons or if the physician has an overly full workload or if the physician is convinced that the necessary relationship of trust has not been formed between the physician and the patient. The physician is, however, obliged to recommend, in the case of agreement, to arrange for a suitable procedure for the continuation of the patient's treatment.

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<sup>8</sup> BEAUCHAMP, Tom L. a James Franklin CHILDRESS. Principles of biomedical ethics. 6th ed. New York: Oxford University Press, 2009.

(5) A physician may not be forced to undertake any medical action or to participate in any such action, which is against the physician's conscience.

(6) A physician may not prescribe medicines which are addictive or which have doping-type effects, for any reason other than for that of medical treatment.

(7) In the case of untreatable illnesses and fatally ill patients, the physician will ease the patient's pain, ensure the patient's human dignity and ease the patient's suffering. In the face of inevitable and expected imminent death, the aim of the medical treatment should not be the extension of life at any cost. Euthanasia and assisted suicides are inadmissible.

(8) In the case of transplantations, the physician will follow the appropriate regulations. The removal of tissue and organs may not be abused for commercial purposes.

(9) In the interests of the patient, the physician is obliged to maintain thorough medical confidentiality with the exception of those cases where the patient frees the physician of this obligation or where the law states otherwise.

(10) A physician who is actively carrying out his or her profession, is obliged to educate him or herself in the specialist field.

(11) A physician is obliged to keep and store thorough documentation in writing or some other form when carrying out his or her profession. In all cases, appropriate protection of the records is required in order to prevent the possibility of their amendment, destruction or abuse.

(12) A physician may not carry out his or her profession in the form of an itinerant practice.

(13) A physician may not, whether it be alone or in conjunction with others, prescribe ineffective curative, diagnostic or other treatments for motives of profit. Within the framework of his or her jurisdiction, the physician may not provide expertly inaccurate statements, which may provide some citizens with unjustified advantages.

(14) If a physician recommends medicines, curative preparations and health care aids in his or her practice, the physician must not do so from a commercial point of view, but exclusively according to his or her conscience and in the interests of the patient.

(15) A physician may participate in the presentation and discussion of medical topics in public, in the press or on television and radio, but must refrain from giving individually targeted advice and making recommendations in his or her own personal favour.

(16) A physician must refrain from all undignified activities which either directly or indirectly involve the promotion of the physician's own person and medical practice and which in consequence amount to agitation aimed at expanding the physician's clientele. The physician may also not initiate any such activities via another party.

(17) New methods of treatment may only be used on patients after sufficient biological trials have been held under conditions which correspond to those set out in the Helsinki Convention and the Nuremberg Codex, and under strict supervision, provided they are not to the detriment of the patient.

(18) A physician should be aware of his or her civic role and influence on his or her environs.

### **§3 The physician and the patient**

(1) A physician will fulfil his or her professional obligations with regard to every patient. The physician will always ensure the provision of the necessary treatments as required by the state of the patient's health and will always do so on time and thoroughly.

(2) A physician will behave correctly and with understanding and patience with regard to the patient and will not lower him or herself to coarse or immoral behaviour. The physician will take the rights of the patient into account.

(3) A physician should refrain from all patronising positions in his or her approach to the patient and accept the patient as an equal partner with all civic rights and responsibilities, including the patient's responsibility for his or her health.

(4) A physician is obliged to inform the patient or the patient's legal guardian of the character of the illness, the intended diagnostic and curative procedures including any risks, the expected prognosis and any further important circumstances which may arise during treatment, in a manner which is comprehensible for them.

(5) A physician may not abuse the patient's trust or dependency in any manner whatsoever.

#### **§4 Relations among physicians**

(1) The basis of the relationship between physicians is mutual honourable, polite and sociable behaviour together with critical fastidiousness, respect for competence and the recognition of the right to a different opinion.

(2) In the interests of the physician's professional honour and with regard to the reputation of the medical profession, a physician may not underestimate the professional skills, knowledge or provided services of other physicians, nor may the physician use demeaning expressions about their personalities or comment on the activities of other physicians in an unsuitable manner in the presence of patients or non-physicians.

(3) A physician will collegially cooperate with those physicians who simultaneously or subsequently examine or treat the same patient. If a physician transfers a patient to another physician for legitimate reasons, the physician must send the new treating physician all the discovered findings and inform him or her of the course of the treatment to date.

(4) A physician is always obliged to request another physician for a second opinion if the circumstances so require and if the patient agrees. The physician is entitled to propose the person to be consulted. The conclusions of the examination for the second opinion should always be documented in writing and it is the physician's responsibility to inform the patient of them with special emphasis, if the two opinions should be different. The physician is entitled to refrain from further treatment if the patient inclines towards the opinion of the physician who provided the second opinion.

(5) A physician must fundamentally carry out his or her practice in person. Another person may only temporarily represent the physician and this must involve a physician who is contained in the list (register) of the Czech Medical Chamber and who fulfils the required specialist requirements.

#### **§5 The physician and the non-physician**

(1) The physician will cooperate with medical workers trained in various specialised activities. If the physician assigns them diagnostic or curative tasks or other procedures, he or she must ensure that they have the qualifications, experience and responsibility to be able to carry out said tasks.

(2) A physician is not authorised to undertake examinations or treatment in the presence of a person who is not a physician and does not belong to the health care personnel. Such people may also not be present during medical operations. Individuals who are training with the doctor, or work in medical fields and further individuals with whose presence the patient has agreed, form an exception to the aforementioned principle, provided there are no medically grounded objections for this being the case.<sup>9</sup>

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<sup>9</sup> [http://www.ceom-ecmo.eu/sites/default/files/documents/czech\\_medical\\_chamber\\_-\\_professional\\_regulation\\_no\\_10.pdf](http://www.ceom-ecmo.eu/sites/default/files/documents/czech_medical_chamber_-_professional_regulation_no_10.pdf) with minor adjustment from HVBK

## 1.1. TASKS REGARDING THE CODE

A. Why have selected parts (in *italics*) of the Code of Ethics been implemented in the Disciplinary Order of the Czech Medical Chamber? Cf. with S. 9 of the Czech Medical Chamber Act, Act No. 220/1991 Coll.:

Each member of the Chamber has the obligation to

- a) exercise his/her profession at a high level of expertise, in accordance with the principles of medical ethics and with the valid legislation,
- b) keep up the Organisation-, Election-, Disciplinary- order and the Rules of Procedure of the Chamber,
- c) pay the membership fees,
- d) inform appropriate organs of the Chamber about changes connected with the medical or pharmaceutical profession,
- e) sign for the responsibility-insurance, in cases laid down by the Chamber.<sup>10</sup>

B. Discuss in groups: What are the five most important obligations written in the Code? Explain.

C. Which bioethical principle, as described by Beauchamp and Childress, do the obligations reflect?

D. Can you think of a legal provision that is actually contrary to a provision of the Code?

## 2. HIPPOCRATIC OATH (ORIGINAL VERSION)

...

With regard to healing the sick, I will devise and order for them the best diet, according to my judgment and means; and I will take care that they suffer no hurt or damage.

Nor shall any man's entreaty prevail upon me to administer poison to anyone; neither will I counsel any man to do so. Moreover, I will give no sort of medicine to any pregnant woman, with a view to destroy the child.

Further, I will comport myself and use my knowledge in a godly manner.

I will not cut for the stone, but will commit that affair entirely to the surgeons.

Whatsoever house I may enter, my visit shall be for the convenience and advantage of the patient; and I will willingly refrain from doing any injury or wrong from falsehood, and (in an especial manner) from acts of an amorous nature, whatever may be the rank of those who it may be my duty to cure, whether mistress or servant, bond or free.....Whatever, in the course of my practice, I may see or hear (even when not invited), whatever I may happen to obtain knowledge of, if it be not proper to repeat it, I will keep sacred and secret within my own breast<sup>11</sup>

<sup>10</sup> <https://www.lkcr.cz/czech-medical-chamber-cmc-443.html>

<sup>11</sup> Available on <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4762847/>. Compare with the current version which is, among other places, available on <https://doctors.practo.com/the-hippocratic-oath-the-original-and-revised-version/>.

## 2.1 TASKS REGARDING THE OATH

- A. What are the rules and bioethical principles for providing care under the Oath?
- B. Explain to what extent the rules are compatible with current Czech legal requirements.
- C. What is the difference between law, morality and ethics?
- D. Is there a country in which it is allowed to kill a patient? If so, what might be the ethical justification?
- E. With the knowledge of S. 9 of Act No. 220/1991 Coll. and the Code of Ethics (see above) of the Czech Medical Chamber, decide whether the Oath is binding upon doctors in the Czech Republic. Bear also in mind footnote no.11

## 3. CASE OF A POLYMORBID PATIENT Vol. 2

An ambulance was called to an 89 year-old polymorbid patient with a wrist fracture. The patient had been suffering from serious cardiac disease, breast cancer, renal insufficiency, incontinence and early stage of dementia. The attending doctor examined the patient in private and came to the conclusion that she was in a terminal stage of her diseases. **The patient did not want to discuss her diagnosis and/or prognosis with the doctor, yet she did not let the doctor know. After being thoroughly informed about her health state, the patient asked the doctor not to tell her daughters, because she wanted to protect them from the tragic news.** After the doctor finished the examination and discussion with the patient, he was approached by the younger daughter of the patient, who was the primary carer and had been living with the patient for years. The daughter told the doctor that she knew her mum was dying, but was begging the doctor not to tell the patient, as it might stress the patient unnecessarily. The daughter strongly believed that the best thing for her mum would be to enjoy her last days or weeks peacefully at home. During the conversation between the younger daughter and the doctor there was a phone call. It was the older daughter of the patient, very much demanding hospitalisation of the patient and care as intensive as possible. **It is against the doctor's conscience to drag the patient to the hospital.**

### 3.1 TASKS REGARDING THE CASE:

- A. Why would a patient not like to know all the information regarding his/her current health state?  
Does a patient have a right not to be informed? How should a doctor proceed?
- B. To what extent should the patient herself decide about her future care? Bear in mind her diagnosis.  
What is a *new person argument* in the context of advance directives?
- C. Is it ethical not to inform the patient that her daughter is aware of the unfortunate prognosis, and vice versa? Please explain.



#### 4. CASE OF A PATIENT SUFFERING FROM LEUKEMIA (5 years old)

In the hospital, there is a 5 year-old child dying of leukemia. The child keeps asking when she is going home and when she is going to join her friends in the kindergarten.

##### 4.1 TASK REGARDING THE CASE:

Divide into roles and argue according to your position:

Parents willing for the doctors to tell the child about her illness and prognosis x doctors not willing to tell anything to the child

Parents trying to persuade the doctors not to tell anything x doctors willing to tell the child about her prognosis



### 3. HISTORY OF THE INFLUENCE OF MEDICAL ETHICS ON CZECH MEDICAL LAW

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Out of the four major principles of bioethics, i.e. non-maleficence, beneficence, autonomy and justice, one could suggest that in the Czech Republic, the importance of the respect for autonomy has increased by the greatest margin. The intended shift from paternalism towards an autonomous approach has been explicitly recognised in the Explanatory Report of the Act on Healthcare Services. However, it still remains questionable whether a Czech patient has sufficient legal support for making autonomous decisions regarding healthcare.

During this Session, we are going to have a closer look at the content and extent of patient autonomy and how it has changed in time. We are going to inspect the legal instruments through which the autonomy of a patient could be exercised and we are going to critically analyse the actual limitations of them. Once again, the Case of polymorbid patient is going to be discussed, with the focus on how the duties of a doctor have changed in time. Besides, the effect of the new Civil Code on the mechanism of patient decision-making is going to be looked at, together with a reflection of the respect for autonomy in the current Criminal Code.

#### 1. PRINCIPLE OF AUTONOMY

Autonomy, as a bioethical concept of the self-determination of a competent patient, has been recognised – as an immanent element of the right to personal freedom, dignity, and private life – via many international human rights conventions <sup>[2]</sup>. However, it still seems to remain a phenomenon typical mainly of the most developed (i.e. so-called 'Western') cultures. Autonomy poses neither a unified content nor a distinct extent worldwide; indeed, the legal framework defining the area for exercising one's autonomy is to be regarded as an entirely national matter, taking into account the unique domestic historical and social background and public interests <sup>[3]</sup> of the relevant country.

The principle of a patient's autonomy in the context of providing medical treatment – of course to some extent deservedly – is widely honoured and considered to be a generally predominant one. Nevertheless, even in the most liberal countries in the world it can be assumed that autonomy should not be understood as a mere enforcement of one's wishes, but as the ability to make rational and mature (therefore also respectable) decisions <sup>[4]</sup>. According to the analyses of national laws, it is precisely the evaluation of the rationality of the expressed wishes which appears to provide the possibility of treating a patient in a paternalistic way, despite his/her right to autonomy.

One of the most crucial difficulties attached to autonomy is undoubtedly the legally guaranteed respect towards it under circumstances in which one's own health or even life could be at risk by exercising such autonomy. Although self-harm or (attempted) suicide of a mentally healthy, competent person – with the great exceptions such as insurance fraud, avoiding military service, financial gain (sale of own kidney) etc. – should not in principle

be sanctioned by law, the law constructs much stricter conditions for the impunity of the active conduct of a third person resulting in the same destructive effect.<sup>12</sup>

### 1.1. TASKS REGARDING THE TEXT PRINCIPLE OF AUTONOMY:

- A. Is autonomy the leading bioethical principle? Should it be?
- B. Is autonomy the leading legal principle? Should it be?
- C. What is/are the legal instrument/s enabling patients' autonomy?

## 2. AUTONOMY OF A PATIENT

Legal source	Legal provision	Term
Act No. 20/1966 Coll., on the Care of the Health of the People S. 23(1)	The doctor is obliged to provide the patient or his/her family members with proper information regarding patient's illness and measures needed, so they can actively cooperate during provision of healthcare.	
Act No. 20/1966 Coll., on the Care of the Health of the People S. 23 (2)	Examination and treatment are performed with the patient's consent or if this consent can be expected.	
Act No. 20/1966 Coll., on the Care of the Health of the People S. 23 (2)	If the patient refuses the necessary care despite a proper explanation, the attending physician will request a written statement regarding the refusal.	
Convention on Biomedicine Art. 5	An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.  This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.	
Act No. 111/2007 Coll. Changing S. 23 of the Act on the Care of the Health of the People S. 23	Healthcare worker qualified to conduct the particular medical profession informs the patients or other entitled persons .... Both about the purpose and nature of provided healthcare and of every medical and therapeutic measure, and about their consequences, alternatives and risks. ...	

<sup>12</sup> The full text was published as PETERKOVÁ, Helena. Autonomy – A leading principle in the end-of-life decision making? Journal of Hospital Administration, 2014, Vol. 3, No. 2, s. 19-23. ISSN 1927-6990.

Legal source	Legal provision	Term
Act No. 372/2011 Coll., Health Services Act S. 28(3)f	The patient has the right ... f) to be informed in advance about the price of health services which are not covered or partially covered by public health insurance and as well about the method of payment, if the health of the patient enables such information to be provided.	
Act No. 372/2011 Coll., Health Services Act S. 34(4)	The patient who has obtained health information or who has renounced the right to health information and who refuses to consent to healthcare services, unless the healthcare services can be provided without the consent of the patient, is repeatedly informed about their health condition to the extent which clarifies that without the healthcare services the patient's health or life may be endangered. If the patient still refuses to consent, he puts the refusal into writing.	
Act No. 372/2011 Coll., Health Services Act S. 32(2)	Unfavourable health information about diagnosis or prognosis of the patient may be withheld - to the extent which is necessary and for a necessary time period only - if there is a reasonable assumption that its disclosure may cause serious harm to the patient, unless ...	
Act No. 372/2011 Coll., Health Services Act S. 32(4)	(4) The patient may withdraw the consent to healthcare. The withdrawal of the consent is not effective if medical intervention has already started and its interruption may cause serious harm to the health or may endanger the life of the patient.	
Act No. 372/2011 Coll., Health Services Act S. 36(1)	The patient may, in case of anticipating a state of health which will not allow the patient to give an informed consent with or refusal of the provision of health services and the way they are provided, express his or her own will ....	
Act No. 372/2011 Coll., Health Services Act S. 32(7)	If the patient cannot – because of his health condition – give a consent to a healthcare service, unless the health service can be provided without consent, the consent of a person designated by the patient according to S. 33 Para 1 is required; if there is not such a person or the person is unreachable, the consent of a spouse or a registered partner is required; if there is not such a person or the person is unreachable, the consent of a parent is required; if there is not such a person or the person is unreachable, the consent of another legal competent next of kin is required if such a person is known.	



## 2.1 TASKS REGARDING THE TABLE:

A. Fill in the following terms into the appropriate fields in the table:

Assumed consent

Informed consent

Substituted consent

Withdrawal of informed consent

Proper information

Information about price of services not funded from public health insurance

Refusal

Therapeutical privilege

Previously expressed wish/living will

B. Explain the shift from paternalism to autonomous approach.

## 3. CASE OF A POLYMORBID PATIENT (Vol. 3)

**In 2000**, an ambulance was called to an 89-year-old polymorbid patient with a wrist fracture. The patient had been suffering from serious cardiac disease, breast cancer, renal insufficiency, incontinence and early stage of dementia. The attending doctor examined the patient in private and came to the conclusion that she was in a terminal stage of her diseases. She asked the doctor not to tell her daughters, because she wanted to protect them from the tragic news. After the doctor finished the examination, he was approached by the younger daughter of the patient, who was the primary carer and had been living with the patient for years. The daughter told the doctor that she knew her mum was dying, but was begging the doctor not to tell the patient, as it might stress the patient unnecessarily. The daughter strongly believed that the best thing for her mum would be to enjoy her last days or weeks peacefully at home. During the conversation between the younger daughter and the doctor there was a phone call. It was the older daughter of the patient, very much demanding a hospitalisation of the patient and as intensive care as possible.

### 3.1 TASK REGARDING THE CASE:

What was the legal duty of the doctor in 2000 towards the patient and her daughters?

## 4. AUTONOMY OF A MINOR

According to S. 35 (1) of the Act on Healthcare Services, the opinion of the minor regarding healthcare services which shall be provided to him needs to be found out. His/her opinion must be taken into account as a factor whose severity increases proportionally with age and degree of intellectual and moral maturity of the minor patient. For consent to the provision of healthcare services for a minor patient, the law on legal capacity of natural persons shall be applied.

According to S. 95 of Act No. 89/2012 Coll., Civil Code, a minor without full legal capacity may, in usual matters, also give his consent to an intervention on his body himself, if this is adequate to the intellectual and volitional maturity of minors of his age, and if it is an intervention not resulting in any permanent or serious consequences.

#### **4.1 CASE OF A PATIENT SUFFERING FROM LEUKEMIA (17 years old)**

A 17 year-old patient P. has been treated for leukemia for more the 10 years, with repeated relapse. Once again, his health state has suddenly deteriorated and marrow stem cell transplant is needed. The patient already experienced it once and strongly refuses to undergo the radiotherapy as conditioning treatment for the transplant. Even though the patient was informed that without the transplant, his chances to survive are limited, he refused the treatment.

#### **4.2 TASKS REGARDING THE AUTONOMY OF A MINOR**

- A. Who is a minor with full legal capacity?
- B. What can a minor patient without full legal capacity decide?
- C. Who can decide on behalf of the minor who does not possess legal capacity for making a decision?
- D. Is the patient P.'s refusal legally valid? Should his refusal be respected?
- E. What if P's parents demand the therapy? What would you suggest?

### **5. AUTONOMY AT THE END OF LIFE**

In the previous criminal law (Act No. 140/1961 Coll., Criminal Act), there existed two crimes against life conducted out of intention: Murder and Murder of Newborn by its Mother. After enacting the new Criminal Code (Act No. 40/2009 Coll.), another crime was added to the list, i.e. Manslaughter:

#### **1961 Criminal Act**

##### **§ 219 Murder**

(1) Whoever intentionally kills another person shall be sentenced to imprisonment for ten to fifteen years.

(2) The penalty of imprisonment for twelve to fifteen years or the exceptional penalty shall be imposed on those who conducted the act referred to in Para (1)

- a) by a particularly cruel or agonising manner,
- b) repeatedly,
- c) to a pregnant woman,
- c) to a person younger than fifteen years of age,
- d) to an official in the service or execution of their competencies,
- g) to another person for their true or presupposed race, belonging to an ethnical group, nationality, political beliefs, religion or because of his/her true or presupposed lack of religious faith,
- j) with the intention to obtain for him-/herself or for another material profit, or in an attempt to conceal or facilitate another criminal offence, or out of other condemnable motives.

#### **2009 Criminal Code**

##### **§ 140 Murder**

(1) Whoever intentionally kills another person shall be sentenced to imprisonment for ten to eighteen years.

(2) Whoever intentionally kills another person with premeditation and after prior consideration shall be sentenced to imprisonment for twelve to twenty years.

(3) An offender shall be sentenced to imprisonment for fifteen to twenty years or to an exceptional sentence of imprisonment if he/she commits the act referred to in Para (1) or (2)

a) on two or more persons,

b) on a pregnant woman,

c) on a child under fifteen years of age,

d) on an official person in the service or execution of their competencies,

e) on a witness, expert or interpreter in connection with the performance of his/her obligations,

f) on a medical worker during performance of the medical profession or employment aimed at saving life or health, or on a person who fulfilled his/her similar obligation of saving life, health or property arising from his/her employment, profession, position or function, or imposed by law,

g) on another person for their true or presupposed race, belonging to an ethnical group, nationality, political beliefs, religion or because of his/her true or presupposed lack of religious faith,

h) repeatedly,

i) by a particularly cruel or agonising manner, or

j) with the intention to obtain for him-/herself or for another material profit, or in an attempt to conceal or facilitate another criminal offence, or out of other condemnable motives.

(4) Preparation is criminal.

#### **§ 141 Manslaughter**

(1) Whoever intentionally kills another person in strong derangement caused by fear, shock, confusion or another excusable mental emotion or as a result of previous condemnable conduct of the aggrieved person, shall be sentenced to imprisonment for three to ten years.

(2) An offender shall be sentenced to imprisonment for five to fifteen years if he/she commits the act referred to in Para (1)

a) on two or more persons,

b) on a pregnant woman, or

c) on a person younger than fifteen years of age.

### **5.2 TASK REGARDING THE AUTONOMY OF A MINOR**

Compare the above provisions of criminal law: Can you see any kind of shift towards allowing euthanasia? Explain.



## 4. MEDICAL ETHICS AND SELECTED FOREIGN MEDICAL LAW

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As already suggested above, bioethics and even more medical law is not an universal phenomenon; they may differ greatly from state to state. The so-called western countries (unlike e.g. China or Vietnam) share to some extent a similar position towards the respect for autonomy of a patient; however, when it comes to highly controversial institutes such as (among others) abortion, surrogacy motherhood, and euthanasia, their legislation varies significantly.

Even though Czech legislation could be evaluated as somewhat liberal, in some aspects it has been criticised for not offering some more progressive solutions. In order to understand foreign approaches and their potential to serve as a bright example, we are going to talk about surrogacy motherhood as a binding contract, two extreme legal positions regarding abortion and our good old friend, the Case of a polymorbid patient, this time as if the patient had a different cultural background and/or the case happened in Netherlands. As a lawyer, one needs to understand the current national law, but also the trends abroad, in order to evaluate legal proposals or to even suggest *de lege ferenda* solutions. Today's session, during which a critical analysis of foreign approaches is to be conducted, should be helpful in that regard.

### 1. SURROGACY MOTHERHOOD

#### 1.1 JOHNSON V. CALVERT CASE (US)

Mark and Crispina Calvert are a married couple who desired to have a child. Crispina was forced to undergo a *hysterectomy* in 1984. Her ovaries remained capable of producing eggs, however, and the couple eventually considered *surrogacy*. In 1989 Anna Johnson heard about Crispina's plight from a coworker and offered to serve as a *surrogate* for the Calverts.

On January 15, 1990, Mark, Crispina, and Anna signed a contract providing that an embryo created by the sperm of Mark and the egg of Crispina would be implanted in Anna and the child born would be taken into Mark and Crispina's home "as their child." Anna agreed she would *relinquish "all parental rights"* to the child in favour of Mark and Crispina. In return, Mark and Crispina would pay Anna \$10,000 in a series of instalments, the last to be paid six weeks after the child's birth. Mark and Crispina were also to pay for a \$200,000 life insurance policy on Anna's life.

The *zygote* was implanted on January 19, 1990. Less than a month later, an ultrasound test confirmed Anna was pregnant.

Unfortunately, relations deteriorated between the two sides. Mark learned that Anna had not disclosed she had suffered several *stillbirths* and *miscarriages*. Anna felt Mark and Crispina did not do enough to obtain the required insurance policy. She also felt abandoned during an onset of *premature labour* in June.

In July 1990, Anna sent Mark and Crispina a letter demanding the balance of the payments due her or else she would refuse to give up the child. The following month, Mark and Crispina responded with a lawsuit, seeking a declaration they were the *legal parents* of the unborn child.

The child was born on September 19, 1990, and blood samples were obtained from both Anna and the child for analysis. The blood test results excluded Anna as the *genetic mother*.<sup>13</sup>

## 1.2 CURRENT LEGAL PROVISIONS (UK):

### Human Fertilisation and Embryology Act from 2008

S. 54

Parental orders: two applicants

(1) On an application made by two people (“the applicants”), the court may make an order providing for a child to be treated in law as the child of the applicants if—

(a) the child has been **carried by a woman who is not one of the applicants**, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,

(b) the **gametes of at least one of the applicants** were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) are satisfied.

(2) The **applicants must be**—

(a) husband and wife,

(b) civil partners of each other, or

(c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.

(3) Except in a case falling within subsection (11), the applicants must apply for the order **during the period of 6 months** beginning with the day on which the child is born.

(4) At the time of the application and the making of the order—

(a) the child's home must be with the applicants, and

(b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(5) At the time of the making of the order both the applicants must have attained the age of 18.

(6) The court must be satisfied that both—

(a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43), have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than **six weeks after the child's birth**.

(8) The court must be satisfied that **no money or other benefit** (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of—

(a) the making of the order,

(b) any agreement required by subsection (6),

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<sup>13</sup> Johnson v. Calvert (1993) [No. S023721. May 20, 1993.]

- (c) the handing over of the child to the applicants, or
- (d) the making of arrangements with a view to the making of the order, unless authorised by the court.

An order relating to the child must not previously have been made under this section or section 54A, unless the order has been quashed or an appeal against the order has been allowed.

(9) For the purposes of an application under this section—

(a) in relation to England and Wales

(i) “the court” means the High Court or the family court, and

(ii) proceedings on the application are to be “family proceedings” for the purposes of the Children Act 1989,]

(b) in relation to Scotland, “the court” means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, “the court” means the High Court or any county court

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which—

(a) relates to a child born before the coming into force of this section, and

(b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife, may be made within the period of six months beginning with the day on which this section comes into force.

#### *Parental orders: one applicant*

(1) On an *application* made by one person (“the applicant”), the court may make an order providing for a child to be treated in law as the child of the applicant if—

(a) the child **has been carried by a woman who is not the applicant**, as a result of the placing in her of an embryo or sperm and eggs or her *artificial insemination*,

(b) **the gametes of the applicant** were used to bring about the creation of the embryo, and

(c) the conditions in subsections (2) to (8) are satisfied.

(2) Except in a case falling within subsection (11), the applicant must apply for the order **within the period of 6 months** beginning with the day on which the child is born.

(3) At the time of the application and the making of the order—

(a) the child’s home must be with the applicant, and

(b) the applicant must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.

(4) At the time of the making of the order the applicant must have attained the age of 18.

(5) The court must be satisfied that both—

(a) the woman who carried the child, and

(b) any other person who is a parent of the child but is not the applicant (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(6) Subsection (5) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her **less than six weeks after the child’s birth**.

(7) The court must be satisfied that **no money or other benefit** (other than for expenses reasonably incurred) has been given or received by the applicant for or in consideration of—

- (a) the making of the order,
- (b) any agreement required by subsection (5),
- (c) the handing over of the child to the applicant, or
- (d) the making of arrangements with a view to the making of the order, unless authorised by the court<sup>14</sup>.

### 1.3 SURROGACY IN THE CZECH REPUBLIC

There is no Czech law regulating surrogate motherhood, except for S. 804 of the Czech Civil Code: Adoption is excluded among persons related in direct line and between siblings. This does not apply in the case of surrogate motherhood.

#### 1.4 TASKS REGARDING SURROGACY MOTHERHOOD:

- A. Explain the terms in italics (the case of *Jonson v. Calvert*).
- B. What is a surrogacy contract?
- C. What are the legal requirements for a surrogacy contract according to UK law? What purpose do the legal requirements serve?
- D. What is an enforceable surrogacy contract?
- E. What are pros and cons of it?
- F. Should a surrogacy agreement be binding and enforceable? Is it in the US, UK and the Czech Republic?

## 2. ABORTION LAW

### 2.1 THE NEW LEGISLATION

The law, which only allows abortion in cases of rape, incest and when the mother's life is in danger, was approved by the X Constitutional Court in October, sparking nationwide protests. The law states that abortions in the case of fetal abnormalities are "incompatible" with X's constitution.

The government has consistently supported the court's verdict, saying that it would halt what it called "eugenic abortions," referring to the termination of fetuses with Down's Syndrome.

Though opponents have accused the Catholic and conservative ruling Law and Justice Party (PiS) of exerting influence over the court in its approval, party leaders say this is not the case. X, a staunchly Catholic country, already had some of the strictest abortion laws in the European Union before approval of the newly tightened measures.

Fewer than 2,000 legal abortions are performed in X each year, with many doctors refusing to perform the operation because of religious convictions. Women's groups estimate that

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<sup>14</sup> Human Fertilisation and Embryology Act 2008, available on <https://www.legislation.gov.uk/ukpga/2008/22/part/2/crossheading/parental-orders>

as many as 200,000 more X women seek abortions each year, either abroad or illegally at home.<sup>15</sup>

## 2.2 TASKS REGARDING THE NEW LEGISLATION

- A. What country stands for abbreviation X?
- B. Which bioethical principles are involved?
- C. What is your personal opinion on the X legislation?

## 2.3 CZECH LAW ON ABORTION

According to Act No. 66/1986 Coll., on Artificial Abortion, a woman who is older than 16 can fill in her application for an abortion within the first three months of her pregnancy. For her application, the woman does not need to have any specific reason, and she can proceed without the permission of her parents. If the woman's age is below 18, the healthcare provider shall notify her parents about the abortion after the abortion has been performed.

After the twelfth week of pregnancy, an abortion can be performed only if the life of the woman is threatened or when it is proven that the fetus is severely damaged or incapable of life. If there are serious medical indications (genetic grounds), the procedure can be carried out up to twenty-four weeks.<sup>16</sup>

Unfortunately, under S. 10 of the Act, artificial abortion cannot be provided to foreigners whose stay in the Czech Republic is only temporary.

## 2.4 TASK REGARDING THE CZECH LAW ON ABORTION

What would be your legal advice to a pregnant lady from X., who is trying to get an abortion on the ground of a severe disability of the fetus?

## 2.5 1967 ABORTION ACT (UK)

S. 1: Medical termination of pregnancy.

(1) Subject to the provisions of this section, a person shall not be guilty of an offence under the law relating to abortion when a pregnancy is terminated by a registered medical practitioner if two registered medical practitioners are of the opinion, formed in good faith—

(a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family; or

(b) that the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman; or

(c) that the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated; or

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<sup>15</sup> <https://www.dw.com/en/XXXXXX-thousands-protest-as-abortion-law-comes-into-effect/a-56363990>, visited in February 2021. Out of study purposes, the name of the country in the link has been removed.

<sup>16</sup> S. 2 (1) and 2. (2) of the Ministry of Health Directive No. 75/1986 Coll.

(d)that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.

## 2.6 TASKS REGARDING THE 1967 ABORTION ACT (UK)

- A. What is your opinion regarding S. 1(1)a of the Act?
- B. What is fatal viability?

## 3. END OF LIFE

### 3.1 CASE OF A POLYMORBID PATIENT (VOL. 4)

An ambulance was called to an 89 year-old polymorbid patient with a wrist fracture, **a member of the Vietnamese community residing in Prague**. The patient had been suffering from serious cardiac disease, breast cancer, renal insufficiency, incontinence and early stage of dementia. The attending doctor examined the patient in private and came to the conclusion that she was in a terminal stage of her disease. **The doctor had reasonable doubts regarding whether the patient could profit from being hospitalised and provided with intensive care.** The younger daughter of the patient, who was the primary carer, strongly believed that the best thing for her mum would be to enjoy her last days or weeks peacefully at home. During the conversation between the younger daughter and the doctor there was a phone call. It was the older daughter of the patient, very much demanding a hospitalisation of the patient and care as intensive as possible.

### 3.2 TASKS REGARDING THE CASE

- A. How might the fact that the patient is Vietnamese affect the perception of informed consent?
- B. How important is the religious/ cultural background of the patient and their family considering the fact that the patient lives in the Czech Republic and she is subject to Czech law?
- C. Imagine that the polymorbid patient asked the doctor to help her die. What are the options of the doctor in the Czech Republic? What if the case happened in the Netherlands?

## 5. ACCESS TO HEALTHCARE

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Medicine has become extremely expensive in recent decades. No country in the world, not even one of the richest ones, can satisfy fully the needs of all patients' treatment, which means that some patients are left without a treatment they could have profited from.

There is no right to be healthy, yet other rights have been recognised: right to (protect) health and right to healthcare.

During this session, we are going to have a look at the most relevant international and national provisions on right to (protect) health and to healthcare, in order to establish whether there is, in practice, a mechanism how to enforce a state to provide a particular patient with a particular treatment, and we are going to discuss in what regard the EU needs to be considered the real gamechanger.

Keeping in mind that healthcare is a scarce resource, we are then going to deal with what is known as rationing (as opposed to rationalisation or optimisation), which sadly became a real day to day issue during the corona virus crisis in the Czech Republic in 2020/2021.

### 1. RIGHT TO (PROTECT) HEALTH AND TO HEALTHCARE

#### 1.1 ART. 12 OF THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
  - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
  - (b) The improvement of all aspects of environmental and industrial hygiene;
  - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
  - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

#### 1.2 WHO CONSTITUTION

Preamble: Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

#### 1.3 ART. 25 OF THE UNIVERSAL DECLARATION OF HUMAN RIGHTS

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

#### **1.4 ART. 11 OF THE EUROPEAN SOCIAL (REVISED) CHARTER**

With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed *inter alia*:

1. to remove as far as possible the causes of ill-health;
2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;
3. to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.

#### **1.4 ART. 35 OF THE CHARTER OF FUNDAMENTAL RIGHTS OF THE EU**

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

#### **1.5 ART. 3 OF THE CONVENTION ON BIOMEDICINE**

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

#### **1.6 ART. 31 OF THE CHARTER OF FUNDAMENTAL RIGHTS AND FREEDOMS OF THE CZECH REPUBLIC**

Everybody has the right to protection of his or her health. Citizens are entitled under public insurance to free medical care and to medical aids under conditions set by law.

#### **1.7 TASKS REGARDING THE RIGHT TO HEALTH AND HEALTHCARE**

- A. Which of these provisions constitutes an actual individual right to health?
- B. Which of these provisions constitutes an actual individual right to (access) healthcare?
- C. What is the role of the European Court of Human Rights?

## **2. ACCESS TO HEALTHCARE FROM EU PERSPECTIVE**

Concerning the European Union, in order to facilitate the free movement of persons, access to healthcare has traditionally been provided not only for workers, but also for their families as well<sup>17</sup>. There has been an attempt to *coordinate* the national social systems<sup>18</sup>.

Moreover, the European Court of Justice has proclaimed patients to be allowed free movement and consequently has dealt repeatedly with the issue of (un)acceptable barriers to patient mobility and the requirement of *prior authorisation* for *cross-border healthcare* as a *prerequisite* for the *reimbursement*. Because the threat of financial instability of respective national systems of healthcare has been acknowledged by the (European Union's) Court of Justice, a state's requirement of prior authorisation for expensive hospital treatment sought by a patient in another Member State than the state of affiliation could be justified.<sup>19</sup>

<sup>17</sup> Council Regulation (EEC) No 1408/71 of 14 June 1971, Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004.

<sup>18</sup> Third Non-Life Insurance Directive (92/49/EEC).

<sup>19</sup> *Müller-Fauré/van Riet C385/99, (2003) ECR I-4409.*



The content of the right to cross-border healthcare, i.e. the right of a patient residing in one Member State to benefit from the healthcare provided in another Member State, was subsequently clarified via the Directive on Patients' Rights in Cross-Border Healthcare<sup>20</sup> (2011/24/EU). Under its Article 8 paragraph 2 it is conceded that 'specific healthcare may be subject to prior authorisation in order to control costs and avoid, as far as possible, any waste of financial, technical and human resources'.<sup>21</sup>

## 2.1 FREE MOVEMENT OF THE PATIENT

You are a resident of the Czech Republic.

A During your holidays in Austria, you broke your leg. You did not have any travel insurance.

B You live with your husband in Denmark where he works. You are in Denmark on a maternity leave, as a Czech employee.

C You live with your husband in Denmark where he works. You are in between jobs, looking for one there.

D You would like to go for a special treatment to Germany.

## 2.2 TASKS REGARDING THE ACCESS TO HEALTHCARE IN EU

A. What is the meaning of the terms in italics?

B. What is the mechanism of financing healthcare in the Czech Republic?

C. Discuss the following in groups: who should pay the healthcare provided to you in Austria and Denmark and under which legal provision (exercise 2.1).

## 3. RATIONING HEALTHCARE

### 3.1 CASE OF BARBARA WAGNER

In 2008, Barbara Wagner, a 64 year-old patient suffering from end-stage of lung cancer, was recommended by her oncologist to undergo a costly, third-line cancer drug Tarceva, as the first and second lines had turned out to be unsuccessful. Barbara Wagner was at that time enrolled in the Oregon Health Plan<sup>22</sup>, the first expressly stated rationing health care system, and according to the existing list of covered treatments, the payment for Tarceva was denied. Simultaneously Barbara Wagner was offered to receive an assisted suicide<sup>23</sup> paid fully from the funds of the Oregon Health Plan.<sup>24</sup> Just for illustration, lethal doses of pentobarbital, which is in Oregon and in Switzerland used for purposes of assisted

<sup>20</sup> Directive on Patients' Rights in *Cross-Border Healthcare* (2011/24/EU) was passed on 9 March 2011.

<sup>21</sup> Published as KREJČÍKOVÁ, Helena. Right to healthcare and the sustainability of the healthcare systems from the European perspective. In: Eds. Baez, Narcisco Leandro a Pavel Šturma. *Mecanismos internacionais e internos de efetividade dos direitos fundamentais*. Joacabe SC: Editora Unoesc, 2014, s. 289-296.

<sup>22</sup> The Oregon Health Plan is a public and private partnership to ensure access to health care for all Oregonians. Since February 1994, Oregon has tried to make Medicaid available to thousands of people who were not eligible even though their income was below the poverty level. Originally, the Oregon Health Plan operated as a five year Medicaid demonstration project, which required a waiver from traditional Medicaid rules. In: *Oregon Health Plan. An Historical Overview*. July 2006. Oregon Department of Human Services.

<sup>23</sup> Treatment under the Death with Dignity Act, which was enacted on 27<sup>th</sup> October 1997.

<sup>24</sup> Waggoner, T.: Oregon Offers to Pay to Kill, but Not to Treat Cancer Patient, *LifeSiteNews.com*, 4.6.2008.

suicide, cost at that time about \$100.<sup>25</sup> Approximately the same price is to be paid for one day on Tarceva, whilst one course of the treatment should last presumably 125 days<sup>26</sup>.

The story was interpreted by the media as an example of shocking and immoral public health economy with no respect for a single human life, when humanity was overwhelmed by cost calculation. The case of Barbara Wagner has been used consistently as a strong contra-argument both for rationing in healthcare and decriminalisation of assisted suicide.

The commentators, presenting themselves as independent and objective observers, added some details to the attractive basic plot, presumably in order to justify to some extent the decision not to provide Barbara Wagner with the Tarceva treatment: first of all, the treatment was meant as experimental, with a 8 % chance to prolong the life of up to 6 months; second, Tarceva is considered an extreme toxic drug, and its severe side effects (diarrhea, rash) arise in every fifth patient irrespective of whether the patient responds to the drug or not; third, in being denied the Tarceva treatment, Barbara Wagner was not granted only the possibility to choose assisted suicide for free, in fact she received a list of many other treatments available for her whose costs would be covered by the Oregon Health Plan, such as palliative care and hospice care; last but not least, after her story had been published, Barbara Wagner was contacted by Tarceva's manufacturer and was with no positive effect treated for free. Soon after starting the drug Barbara Wagner died, and her death was rendered as proof of the futility if not even insanity of the treatment.<sup>27 28</sup>

### 3.2 TASKS REGARDING THE CASE

- A. According to your opinion, was it a good idea to provide Barbara with the treatment?
- B. What is rationing? What is rationalising?
- C. What is equity? What is equality?
- D. Is there a need to ration healthcare? Why? Why not?

### 3.3 RATIONING IN THE CZECH REPUBLIC

Due to the pandemic caused by the corona virus, the Czech healthcare system is at the edge of collapse. At one moment, there are three ambulances coming with three critically ill patients in need of a ventilator:

A single mum of five kids, at the age of 35; a business man, employer of 20 people, at the age of 22;

the President of the Czech Republic, at the age of 77.

Unfortunately, there is just one ventilator available.

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<sup>25</sup> Marker, R. L., Hamlon, K.: Euthanasia and Assisted Suicide: Frequently Asked Questions, Patients' Rights Council, January 2010, available at: <http://www.patientsrightscouncil.org/site/frequently-asked-questions/>.

<sup>26</sup> According i.e. to the NICE technology appraisal guidance 162: Lung cancer (non-small-cell) - erlotinib: NICE 2008, at p. 2.

<sup>27</sup> Attig, R.: Sensationalizing a sad case cheats the public of sound debate, LiveOregon.com, 29.11.2008.

<sup>28</sup> The whole text published as PETERKOVÁ, Helena. Rationing - a Marginal Argument in the End of Life Debate? Lex Medicinæ - Revista Portuguesa de Direito da Saúde, 2011, roč. 8, č. 16. s. 67-77.

## 1.1.2 TASKS REGARDING RATIONING IN THE CZECH REPUBLIC

A. Who should be treated, based on the following criteria?

First come, first served.

Better prognosis.

Health insurance.

Age.

Sex. (Ladies first.)

Social status / profession.

Lottery.

B. According to the ethicist David Černý from Ústav státu a práva Akademie věd ČR, the scarce resources should be allocated to patients

1. who have the best chance to survive and recover

2. among them, the ones who are healthcare workers

3. among the ones who are healthcare workers with the best chance of recovery, through lottery.<sup>29</sup>

Do you agree?

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<sup>29</sup> <https://domaci.ihned.cz/c1-66885910-lekarum-hrozi-ze-budou-vybirat-koho-zachrani-je-mi-jich-hrozne-lito-v-teto-situaci-nemuseli-byt-rika-etik-cerny>

## 6. BEGINNING OF LIFE

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The sanctity of life has been recognised by many international and national documents on human rights and shall not *per se* be questioned. Yet there are legitimate disputes regarding the very definition of life, such as when the life of a human being begins i.e. from which moment the life shall be protected and under which circumstances.

With full respect for everybody's personal individual opinion on that, we are going to discuss the legal provisions on the protection of an embryo and fetus and the reasoning behind them, together with the legal definition of the beginning of life and its legal consequences. Furthermore, we will spend some time on medicalisation of conception and its legal and ethical aspects, such as whether there is/should be a right for a parent to conceive a baby genetically related to the parent. Last but not least, we will discuss the situation when a birth of a child is actually not considered a blessing, and the fact that the child was born constitutes a harm.

### 1. PROTECTION OF EMBRYO

#### 1.1 CURRENT LEGAL PROVISIONS (CZE)

##### **Article 18 of the Convention on Biomedicine: Research on embryos *in vitro***

1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
2. The creation of human embryos for research purposes is prohibited.

##### **S. 8 (3) of Act No. 227/2006 Coll. On Research on Human Embryonic Stem Cell:**

For the purpose to obtain human embryonic stem cell, only those spare embryos could be used which are not older than **7 days** (excl. the cryo-conservation).

#### 1.2 TASKS REGARDING THE PROTECTION OF EMBRYO

A. Based on the definition of a fetus (see below), do you agree that an embryo should be protected?

Fetal development occurs between the embryonic stage of development and birth in humans. This stage begins after 11 weeks of gestation, when the embryo begins to exhibit human characteristics, and lasts until birth.<sup>30</sup>

B. What are spare embryos?

C. Why is it not allowed to use spare embryos older than 7 days?

### 2. MOMENT OF BEGINNING OF LIFE

According to Art. 6(1) of the Czech Bill of Fundamental Rights and Freedoms, everyone has the right to life. Human life deserves protection even before birth.

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<sup>30</sup> <https://biologydictionary.net/fetus/>

## 2.1 TASKS REGARDING MOMENT OF BEGINNING OF LIFE

A. When does life begin? Explain your position.

At the moment of conception

After 12 weeks of pregnancy

When the labour starts

When the baby starts to depart the mother's body

When the baby is completely departed from the mother's body

B. What would be the legal consequences in every particular case mentioned above?

C. On 28. 1. 2013 patient A. birthed her child at the obstetrics department in Hospital XY. The patient claims she was subjected to medical treatment without her consent. Attending healthcare workers did not respect her wishes, ignored her birth plan which was written in advance, and did not inform her about measures which were carried out. The patient especially complained about being provided an episiotomy (surgical incision of the perineum and the posterior vaginal wall) and Kristeller's expression (pressing on the uterine fundus in order to facilitate a vaginal delivery). and extraction of the placenta after the birth. According to the patient, these measures were unnecessary, *non lege artis* and resulted in massive bleeding which endangered her life.<sup>31</sup>

Were the healthcare workers allowed to intervene against A.'s will and if so, under which justification?

## 3. ASSISTED REPRODUCTION

### 3.1 SURROGACY IN THE CZECH REPUBLIC FOR SINGLE MEN AND GAY COUPLES

(ADVERTISEMENT)

After several years of working with surrogacy processes in Ukraine, we have expanded our operation to include a service offering gestational surrogacy in the Czech Republic.

The option Surrogacy Czech Republic is exclusively open to single men and gay couples who need IVF with an egg donation to build their families. This programme is a collaboration between ilaya and our partners in the Czech Republic and Ukraine and together we will provide you with information and support throughout the entire process.

Egg donation in the Czech Republic is anonymous, regulated by law and based on medical requirements. No biological material will be taken from the chosen surrogate.

The surrogate is not anonymous – the couple will meet the surrogate and can choose to be in touch with her during the process. <sup>32</sup>

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<sup>31</sup> I. ÚS 1565/14

<sup>32</sup> <https://ivf.ilaya.com/surrogacy-czech-republic/>

### 3.1 TASKS REGARDING THE SURROGACY ADVERTISEMENT

A. Is the activity advertised above legal in the Czech Republic? Argue whilst considering the legal regulation on assisted reproduction, as shown below:

According to S. 3(4) of the Act on Specific Health Services, for the artificial insemination of a woman, the woman's eggs could be used, sperm could be obtained from the man who is undertaking the treatment together with the woman, or reproductive cells could be obtained from an anonymous donor.

B. Is the advertisement ethical? Evaluate the current legal regulation on assisted reproduction.

## 4. WRONGFUL BIRTH/ WRONGFUL LIFE ACTION

### 4.1 WRONGFUL BIRTH

In the Czech Republic, wrongful birth actions have been strongly debated mainly due to two recently published cases - the first concerning the unwanted birth of one child after an abortion of twins which was not carried out properly, while the second concerned the birth of a child after a properly conducted sterilisation. In both cases the children were born healthy.

*Wrongful birth* can be described in a broad sense as any unwanted child birth occurring on the basis of a breach of the legal duty of a doctor. Thus, wrongful birth can be used in the case of the birth of a completely healthy child as well as a disabled child; regardless whether the birth occurred due to an unwanted conception (so-called *wrongful conception*) or unwanted continuation of pregnancy (so-called *wrongful pregnancy*).

In contrast, sometimes - especially in common law - the term wrongful birth is used *stricto sensu* in the case that a child is born disabled and either the disability of the child was not established by the attending doctor or the contraceptive methods and/or abortion were provided improperly by the attending doctor.<sup>33</sup>

Therefore, when discussing wrongful birth, the following situations could be distinguished:

- the parents were not properly informed of the (risk of) harm, and therefore they did not use any contraceptive method or the mother did not undergo an abortion respectively, and
- the parents were aware of the genetic predisposition to developmental defects of the fetus or even of the defects themselves, yet the contraceptive method or abortion failed due to medical malpractice of the attending doctor.

As foreign case law indicates, to impose any legal liability on a doctor (usually a gynecologist or surgeon) because of the unwanted birth of a disabled child, a breach of

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<sup>33</sup> This situation, i.e. wrongful birth, shall be clearly distinguished from so-called *wrongful life*. The doctrine of wrongful life presumes that the life of a severely disabled child is not - because of the unbearable pain and suffering of the child - worth living. Therefore, according to the doctrine, the child should have never been born. It is thus the child itself (and not its parents) who claims damages consisting of the fact that the child is alive. As is obvious, wrongful life actions are extremely controversial; this is why they are unacceptable in most countries and rejected by the courts.

a legal obligation is required, as well as a causal link between the unlawful consequence (e.g. the birth of a disabled child) and the misconduct of the doctor (either a failure to properly inform the parents of the (potential) abnormal development of the fetus, or a non lege artis sterilisation or vasectomy or abortion).

Parents of an unwanted disabled child are entitled to seek damages to compensate them for their expenses for the special care of a child with abnormal needs. Parents are also entitled to claim immaterial harm caused by the birth of an unwanted disabled child.

It is quite obvious that the wrongful birth factual constellation must be strictly differentiated from a situation where harm to the fetus is itself caused by the unlawful conduct of a doctor (e.g. malpractice during the delivery). In these cases the liability of the doctor is to be designed in a completely different way – particularly as liability for injuries caused to the health of the child.

It can be concluded that financial compensation for the parents for an unwanted child is seen by the courts as compensation for the unlawful interference with the parental autonomy of the parents, their right to privacy and family life. However, the courts are much more reluctant to declare a healthy child as a material loss. Thus the German Federal court in its quite controversial judgement considered the living costs of the healthy child to be a material loss, not the child itself.<sup>34</sup> A very similar approach is to be found also in Switzerland<sup>35</sup> and in the Netherlands<sup>36</sup> which, however, is from international perspectives somewhat exceptional.

In the Czech Republic, there is at the moment no judicial consensus on whether the birth of a healthy child may under certain circumstances constitute an unlawful interference with the rights of the mother. According to the decision of the Court of Appeal in Olomouc regarding the abortion of just one twin, (somewhat symbolic) compensation for the mother is adequate, whereas according to the decision of the Court of Appeal regarding pregnancy after sterilisation, any compensation for the mother for having a healthy child would be immoral.

As long as the decision of a woman's own pregnancy meets the statutory conditions,<sup>37</sup> not providing the abortion properly would breach the right of the woman not only to proper healthcare, but also to her private and family life, as could be subsumed under s. 80 of Act No 89/2012 Coll., Civil Code.

The right of the paternal autonomy of a pregnant woman, i.e. the right to have her pregnancy terminated, applies regardless of whether the fetus is healthy or is suffering from a congenital defect; if violated, the liability of the doctor arises. Unlawful interference

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<sup>34</sup> The judgement of the German Federal Court BGHZ 143,389, NJW 2000, 1789. To hold a doctor liable for wrongful birth, it must be proven that the patient had contacted the doctor specifically due to family planning (consulting, abortion, etc.), i.e. the doctor was supposed to be a guarantor of no pregnancy, and the doctor breached his duties towards the patient (the principle of so-called preventive purpose of the legal relationship – *Schutzzweck des Behandlungsvertrags*). Cf. the decision of the 2nd senate of the German Constitutional Court BVerfGE 88, 203, 296, which stated that in accordance with the value of human dignity, no (material) loss arises from the existence of a child.

<sup>35</sup> BGE 132 III 359.

<sup>36</sup> Hoge Raad DJZ 1997, 893 = AJP 1997, 1145 ff.

<sup>37</sup> S. 4–6 of Act No 66/1986 Coll., on abortion.

with the right to privacy and family life may be constituted by improper care and/or insufficient information provided to the patient.

#### 4.2 CASE OF GLEITMAN V. COSGROVE

Sandra Gleitman was examined by Dr. Robert Cosgrove, Jr. and found by him to be two months pregnant. She informed him that on or about March 20, 1959 she had had an illness diagnosed as German measles (rubella). Mrs. Gleitman testified that Dr. Cosgrove, on receipt of this information and on inquiry by her, told her that the German measles would have no effect at all on her child.

For the next three months Mrs. Gleitman received her prenatal medical care from the army doctors at Fort Gordon, Georgia, where her husband was stationed. She informed the army doctors about the German measles she had had in her early pregnancy, and they instructed her to ask her regular physician about this when she returned home.

...

On November 25, 1959 Mrs. Gleitman birthed a boy, Jeffrey, at the Margaret Hague Maternity Hospital in Jersey City. Although at first the baby seemed normal, a few weeks later the substantial defects which Jeffrey has in sight, hearing, and speech began to become apparent. He has had several operations which have given him some visual capacity, and he attends a special correctional institute for blind and deaf children. His physical condition, which is seriously impaired, is not in dispute on this appeal.

Plaintiffs' medical expert, Dr. Louis Fraulo, gave his opinion that Jeffrey's condition was causally related to the viral disease of German measles which Mrs. Gleitman had in March. Dr. Fraulo testified that women who have German measles in the first trimester of their pregnancy will produce infants with birth defects in 20 to 50 per cent of the cases.

...

In the present case there is no contention that anything the defendants could have done would have decreased the likelihood that the infant would be born with defects. The conduct of defendants was not the cause of infant plaintiff's condition.

The infant plaintiff is therefore required to say not that he should have been born without defects but that he should not have been born at all. In the language of tort law he says: but for the negligence of the defendants, he would not have been born to suffer with an impaired body. In other words, he claims that the conduct of defendants prevented his mother from obtaining an abortion which would have terminated his existence, and that his very life is "wrongful."<sup>38</sup>

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<sup>38</sup> Gleitman v. Cosgrove, 49 N.J. 22 (1967).



### **4.3 CASE OF CONTRACEPTIVE A.**

On 16 July, the patient came for a preventive gynecological examination during which, inter alia, cytological smears of the cervix were taken with suspicious results. Therefore, a control examination after 3 months was recommended to the patient. At that time, the patient was months after her 3<sup>rd</sup> childbirth, breastfeeding, without menstruation, and regularly using hormonal contraception A.

As part of cancer prevention, the patient was invited by her doctor to control smears on 24 November. On that day, she was also examined by palpation. Further contact between the patient and the doctor took place on 21 December, when the patient came for another prescription of contraceptives. On 11 January the patient visited the doctor because she was feeling peculiar and it turned out at that time that she was 18 weeks pregnant.

### **4.4 TASKS REGARDING THE WRONGFUL BIRTH/WRONGFUL LIFE ACTION**

- A. What are the main differences between wrongful birth and wrongful life actions?
- B. Analyse the case of contraceptive A.
- C. Why as a rule is wrongful life action not accepted by courts worldwide? Is there something wrong with the concept of wrongful life?

# 7. HUMAN BODY AND ITS PARTS

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The main focus of this session is the legal and ethical aspects of transplantation, in order to show that even after decades of experiences, there are still hard cases regarding the decision whether a transplantation should take place, especially if an incompetent patient and/or minor is concerned.

Besides, we will also look at another controversial issue involving a part of the human body - the fights over getting the placenta after giving birth, either in order to bury it as some kind of ritual, or to use it for healing purposes.

## 1. CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

### Organ and tissue removal from living donors for transplantation purposes

#### Article 19 – General rule

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.
2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

#### Article 20 – Protection of persons not able to consent to organ removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.
2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:
  - i. there is no compatible donor available who has the capacity to consent;
  - ii. the recipient is a brother or sister of the donor;
  - iii. the donation must have the potential to be life-saving for the recipient;
  - iv. the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;
  - v. the potential donor concerned does not object.

### Chapter VII – Prohibition of financial gain and disposal of a part of the human body

#### Article 21 – Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

#### Article 22 – Disposal of a removed part of the human body

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

## 1.1 TASKS REGARDING TRANSPLANTATION IN GENERAL

- A. What is an organ? What is tissue?
- B. What organs can be removed from a living donor?
- C. What is regenerative tissue?
- D. What is xenotransplantation and from whom/what could it be used?
- E. Does a donor deserve to be paid for his/her donation? Explain.
- F. What is opt in, opt out, mandatory choice? What solution would you prefer?

## 2. CASE OF A SISTER'S KEEPER

Kate Fitzgerald has acute promyelocytic leukemia. As neither her parents, firefighter Brian and lawyer Sara, nor older brother Jesse are a genetic match, Dr. Chance, Kate's oncologist, suggests designer in vitro fertilization. Anna is born as a *savior sister*.

Beginning with the harvest of her umbilical cord, over the next 11 years Anna donates compatible organs, blood, stem cells and tissue to Kate. Anna's life is one of hospitalisations, growth hormone injections, opioid painkillers, sleeping pills, bleeding, and infections. While Sara has no qualms over using Anna's body to treat Kate's, Brian is closer to Anna and has misgivings over their treatment of her.

At age 15, Kate goes into kidney failure and Anna knows she will be required to *donate* one of hers. She realizes that having just a single kidney will restrict her life, precluding playing sports, drinking alcohol, maybe even having children, and putting her at risk should her one remaining kidney ever have an issue.<sup>39</sup>

## 2.1 TASKS REGARDING THE SISTER'S KEEPER CASE

- A. What is a savior sibling?
- B. What do you think about Anna's situation?
- C. Choose a role: Anna, Sara (the mum), Brian (the father), Kate

According to your role, argue what is in your best interest.

What would you say in a court hearing regarding donation of Anna's kidney?

## 3. CASE OF STRUNK V. STRUNK

Arthur L. Strunk, 54 years of age, and Ava Strunk, 52 years of age, of Williamstown, Kentucky, are the parents of two sons. Tommy Strunk is 28 years of age, married, an employee of the Penn State Railroad and a part-time student at the University of Cincinnati. Tommy is now suffering from chronic glomerulus nephritis, a fatal kidney disease. He is now being kept alive by frequent treatment on an artificial kidney, a procedure which cannot be continued much longer.

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<sup>39</sup> The plot of the American drama movie called My Sister's Keeper, as described on [https://en.wikipedia.org/wiki/My\\_Sister%27s\\_Keeper\\_\(film\)](https://en.wikipedia.org/wiki/My_Sister%27s_Keeper_(film)).

Jerry Strunk is 27 years of age, incompetent, and through proper legal proceedings has been committed to the Frankfort State Hospital and School, which is a state institution maintained for the feeble-minded. He has an I.Q. of approximately 35, which corresponds with the mental age of approximately six years. He is further handicapped by a speech defect, which makes it difficult for him to communicate with persons who are not well acquainted with him. When it was determined that Tommy, in order to survive, would have to have a kidney the doctors considered the possibility of using a kidney from a cadaver if and when one became available or one from a live donor if this could be made available. The entire family, his mother, father and a number of collateral relatives were tested. Because of incompatibility of blood type or tissue none were medically acceptable as live donors. As a last resort, Jerry was tested and found to be highly acceptable. This immediately presented the legal problem as to what, if anything, could be done by the family, especially the mother and the father, to procure a transplant from Jerry to Tommy. The mother petitioned the county court for authority to proceed with the operation.<sup>40</sup>

### 3.1 TASKS REGARDING THE STRUNK V. STRUNK CASE

- A. Should the kidney be transplanted? Explain your position.
- B. Could there be an analogy between the reasoning in the Strunk v. Strunk case and the Sister's Keeper case?

## 4. CASE OF HANNAH JONES

Hannah Jones, a terminally ill 13 year-old girl who suffers from a rare form of leukemia, told doctors that she believed the treatment was too risky and that she would prefer to enjoy her remaining days in the company of family and friends.<sup>41</sup>

### 4.1 LEGAL REGULATION IN THE CZECH REPUBLIC

#### S. 95 of the Czech Civil Code:

A minor without full legal capacity may, in usual matters, also give his consent to an intervention on his body himself, if this is adequate to the intellectual and volitional maturity of minors of his age, and if it is an intervention not resulting in any permanent or serious consequences.

### 4.2 TASKS REGARDING THE CASE OF HANNAH JONES

- A. What would Hannah's legal position be in the Czech Republic? Explain based on S. 95 of the Czech Civil Code.
- B. What if you knew that she would change her mind?

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<sup>40</sup> Strunk v. Strunk 445 S.W.2d 145 (1969)

<sup>41</sup> Available on: <https://www.independent.co.uk/life-style/health-and-families/health-news/girl-13-wins-right-to-refuse-heart-transplant-1009569.html> (accessed in February 2021)

## 5. CASE OF A WITHHELD PLACENTA

After giving birth to her daughter, A. asked the hospital to be provided with the placenta so she can take it home and make a healing extract out of it afterwards, when she gets home. It was of the highest importance for the patient to get her placenta, because the labour was complicated, ended up by C- section, and the patient feels extremely weakened.

### 5.1 LEGAL REGULATION IN THE CZECH REPUBLIC

The relevant legal provisions are (as found below): S. 111 and 112 of the Czech Civil Code, and S. 81 and 82 of the Act on Healthcare Services:

#### Civil Code:

##### Section 111

(1) An individual whose body part has been removed has the right to know how it has been disposed of. Disposing of removed body parts in a way which is undignified for the individual or which endangers public health is prohibited.

(2) A removed part of an individual's body may, with his consent, be used during his lifetime for medical, scientific or research purposes. Using a removed body part of an individual for a purpose of an unusual nature always requires his express consent.

(3) What applies to human body parts shall also apply, by analogy, to anything that proceeds from the human body.

##### Section 112

An individual may leave a part of his body to another only under conditions laid down by other legal regulations. This does not apply in the case of hair or similar parts of the human body, which can be painlessly removed without anaesthesia and which are naturally restored; they may be relinquished to another, even for remuneration, and are considered to be a movable thing.

#### Act on Healthcare Services:

##### Section 81

(1) A part of the body removed from a patient during providing of healthcare or the body of a deceased patient, including parts removed from the body of the deceased, may be stored and used

- a) for the needs of science, research or for educational purposes in healthcare,
- b) for therapeutical use regarding a recipient of human tissues and cells pursuant to the Act on Human Tissues and Cells,
- c) for the needs of transplants according to the law regulating transplants,
- d) for use in the production of medicines pursuant to the Act on Medicinal Products and pursuant to the Act on Human Tissues and Cells,
- e) for needs specified by other legislation.

(2) For the purposes of

(a) paragraph 1 (a), (b), (d) or (e), a part of the body removed from a patient whilst providing healthcare may be used if

1. the patient has been informed by the healthcare provider regarding the possibility of its storage, donation and use, and the patient has given a verifiable consent to it in accordance with this Act, and
2. in the case of use for the purposes referred to in paragraph 1 (a), (b) or (d) the conditions under the Human Tissues and Cells Act have been met,

(b) paragraph 1 (a), (b), (d) or (e) the body of the deceased, including parts removed from the body of the deceased, may be used if

1. the deceased has given his/her verifiable consent in accordance with this Act during his/her lifetime,
2. in the case of use for the purposes referred to in paragraph 1 (a), (b) or (d) the deceased has been informed during his/her lifetime of the possibility of donating tissues or cells for these purposes, their collection, storage and use, and the conditions under the Human Tissues and Cells Act have been met; and
3. the purpose of the autopsy will not be defeated, especially in cases where the death is suspected to be caused by crime or suicide;

if the deceased has not given verifiable consent during his/her lifetime, the next of kin of the deceased may give verifiable consent.

(3) On the basis of the request of the attending physician or legal representative or guardian of the patient, the provider performing the pathological-anatomical autopsy shall provide the collected biological material for the provision of a consulting service pursuant to § 2 para. b) another provider in the field of pathological anatomy.

(4) Consent is not required in the case of

(a) the use of biological material for the purposes of teaching, science or research taken from a patient in the course of healthcare or in connection with autopsy from the body of the deceased, unless the biological material or its use in teaching, science or research provides information through which it would be possible to identify the patient or the deceased; in the case of the use of biological material for teaching, science or research in the field of genetics, the procedure shall be in accordance with other legislation governing specific health services,

(b) life-saving medical training for a coniotomy or puncture of tension pneumothorax, which may be performed only in the context of a pathological-anatomical autopsy or medical autopsy and provided that the purpose of the autopsy is not defeated, in particular where there is a suspicion death has been caused by crime or suicide.

(5) Proof of consent to the preservation and use of a part of the patient's body or the body of the deceased, including parts removed from the body of the deceased, means

(a) a written consent of the patient or of the deceased during his/her lifetime or of a next of kin of the deceased with their officially verified signature, or

b) a written record of the patient's consent as expressed in the medical facility; the record is signed by the patient and the healthcare professional; if the patient is unable to sign the record due to his medical condition, his undoubted expression of will shall be signed by the healthcare professional and a next of kin of the patient and, if not present, by a witness; the record shall state the manner in which the patient expressed his/her will and the medical reasons preventing the patient's signature.

Written consent or a written record of the consent and a record of the submission of information pursuant to paragraph 2 letter (a) point 1 or paragraph 2 (a); (b) point 2 is part of the medical records kept on the patient; part of the consent is to determine the purpose of use.

(6) A part of the patient's body or the body of the deceased, including parts removed from the body of the deceased, may be stored and used only if the health of another person is not endangered. In order to achieve that, the medical state of the patient or deceased shall be assessed. Unless otherwise provided by other legislation, the assessment of the medical state is the responsibility of the provider who provides the health services under which the removal was performed.

(7) The use of a part of the patient's body or the body of the deceased, including parts removed from the body of the deceased, cannot be a source of financial or other compensation or other benefits for anyone. This does not preclude the reimbursement of purposefully, economically and demonstrably incurred expenses incurred in direct connection with the handling of a part of the patient's body or the body of the deceased, including parts of the body of the deceased, i.e. their procurement, examination, storage and processing.

## Section 82

(1) During disposing of a fetus after abortion, which was not as human remains delivered to be buried according to the law on funeral services, and further of fetal egg without an egg and fetal placental bed, which were removed or expelled from a woman, the provisions of Section 81 shall apply mutatis mutandis, with the specification that the fetus after abortion may be used only for the needs of science, research or for educational purposes.

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### 5.2 TASK REGARDING THE CASE OF PLACENTA

Decide whether you, as a healthcare provider, can/may satisfy the wish of the patient.



## 8. MEDICAL RESEARCH

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Medical research is an important and beneficial activity which is, however, connected to an inherent risk of adverse events. From its very nature, research aims at gaining knowledge on a particular intervention's safety and efficiency, so these cannot be fully guaranteed to those who participate in a research study. For this reason, the law regulates research so the risks to its participants (subjects) do not exceed the limits considered permissible by the society.

In this session, we will first discuss the basic ethical framework of medical research involving human participants. Then, we will discuss several topics. We will use fictional cases as starter points – but similar cases theoretically could happen, either now or in the past.

There are three main branches of medical research. Under Czech law, they are called clinical research of medicinal products, clinical evaluation of medical devices (machines, equipment, materials, etc.), and evaluation of new methods not yet established in clinical practice (for example a new type of surgery such as a womb transplant). While there are many important differences between the three branches, the basic ethical questions and considerations are arguably the same.

### 1. CASE 1 – THE FUNDAMENTAL DILEMMA

A very deadly pandemic is raging on, causing the death of about 15 per cent of any population it hits. Millions of people die of the disease and the lives of many other millions are in danger. A rogue scientist develops a risky gene therapy which safety has never been tested before and applies it to a child without the full informed consent of his parents. After that, he deliberately exposes the child to the deadly virus which causes the pandemic. Fortunately, the child remains healthy and the therapy proves effective, eventually saving countless lives.

Question to ponder:

Do you consider the conduct of the “rogue scientist” ethical? Why or why not?

#### 1.1 REAL INSPIRATION – THE ORIGIN OF VACCINATION

While the story above is fictional, it is loosely inspired by real events. In the end of the 18th century, smallpox killed around 10-20 per cent of the population in Northern England. People noticed that those who worked closely with cows – which were known to spread cowpox – were much less likely to get ill with smallpox and to die of it. Cowpox seemed to somehow immunise people against much more dangerous smallpox.

In 1796, physician Edward Jenner infected James Phipps (the eight year-old son of his gardener) with the much less dangerous cowpox. Afterwards, James was deliberately infected with smallpox more than twenty times but never got ill. James Phipps died almost 60 years later, living in a house lent by Dr. Jenner.

Interestingly, the term cowpox is *Variolae vaccinae* in Latin since the Latin word for a cow is *vacca* – the word vaccination comes from this. What is important, though, is that with Dr. Jenner's experiment, the era of vaccination began, saving countless millions of human



lives in the centuries to come and ultimately changing the world. The experiment was immensely beneficial and by contemporary standards at that time, it was considered ethical. Nevertheless, a similar experiment would not be ethically permissible today (unless the ethical and legal standards would dramatically change, for example as a result of a pressing health need).

## 1.1 THE BASIC DILEMMA OF RESEARCH

Every research on human beings faces the basic dilemma: the need for balancing the potential benefits of such research with its risks. This question has been contemplated for many centuries. Even some of the great physicians of the Middle Ages, such as Maimonides and Avicenna, were paying attention to it. Maimonides got very close to our current understanding of medical research ethics when he stated that the patient must be considered an end in himself and not a mere means to expand knowledge.

The dilemma has further been addressed in many ethical and legal documents in the modern age. The rise of modern medical ethics is evident in the Prussian Minister of Interior's directive of 1891 and the German Guidelines for Human Experimentation of 1931. More relevantly for today, the Nuremberg Code of 1947 established ten basic principles for human experimentation. While the Nuremberg Code is not binding, its principles are still used in many treaties and documents. Nevertheless, the sharp rise of interest in medical research ethics in the Western World came with several scandals regarding unethical research on patients in the USA in the late 1960s.

Nowadays, there are several important international documents on medical research such as the World Medical Association's Declaration of Helsinki, the Good Clinical Practice, and the Universal Declaration on the Human Genome and Human Rights. Related questions are also regulated by several broader international conventions such as the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. Perhaps the most famous international document related to medical research (and medicine in general) is 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 (also known as the European Convention on Human Rights and Biomedicine). Its Article 2 makes it very clear what position it takes with regard to the fundamental research dilemma when it states: *"The interests and welfare of the human being shall prevail over the sole interest of society or science."*

## 2. CASE 2 – INFORMED CONSENT

Mr. Jack (34) has moderate mental retardation because of which he lives with his loving brother Peter (31) who is his guardian. Since Mr. Jack's legal capacity was deemed limited by the court, he cannot grant consent to intervention to his physical integrity. Mr. Jack has also suffered from epilepsy since childhood. One day, Mr. Jack's neurologist informs his guardian Mr. Peter of a clinical trial of a new medicinal product that is very promising in preventing epileptic seizures. The medication is in the 3<sup>rd</sup> stage of clinical trial (just before registration) and the known risks are very low. Mr. Peter enthusiastically gives informed consent. However, Mr. Jack refuses to take the medication, wildly gesticulates and shouts that he does not want to eat the pills. Obviously, he does not fully understand the meaning of the treatment, so his guardian and Dr. William, the clinical trial investigator (the

physician conducting the trial) do not take his uninformed disapproval seriously. Mr. Peter uses his authority over Mr. Jack, scolds him and holds his hands when the pills are given to him. Then Mr. Peter orders Mr. Jack to swallow his pills and behave better next time. This goes on for two long weeks after which Mr. Jack finally submits to Mr. Peter 's will and stops his attempts to avoid the medication.

Questions to ponder:

How would you evaluate Mr. Peter's and Dr. William's behaviour from the ethical perspective, and why?

Try to solve the case from the legal perspective. You can base your analysis mainly on Articles 5, 6, 16, and 17 of the European Convention on Human Rights and Biomedicine. You can also find relevant provision(s) in Act No. 378/2007 Coll., on Pharmaceuticals, and Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.

### **CASE 3 – THE ROLE OF FORTUNE**

Mrs. Fiona (45) suffers from third stage cancer. Her cancer is very rare: there exists no registered therapy for this stage. She learns about a new clinical trial of very promising immunotherapy. Eagerly, Mrs. Fiona decides to participate as a research subject. She is informed that she might be randomly put in a control group of patients who would be given a placebo instead of any effective therapy. Knowing that without the trial her chances of survival are extremely low, Mrs. Fiona signs an informed consent form. Despite her hopes, her health does not improve. Finally, she learns that she was really put in the control group by the computer so she never received the tested drug. Her relatives want to sue the sponsor of the trial (the pharmaceutical company who finances the trial) or the provider of health services who owns the facility where the trial is conducted. Both potential defendants argue that because there was no registered therapy for the third stage of Mrs. Fiona's cancer, the use of a placebo was necessary for the study to comply with scientific standards of randomised controlled trials. Mrs. Fiona seems to accept the situation, saying that she is glad she had at least some hope and that she does not blame anyone. After her death, her relatives sue both the sponsor and the provider of health services.

Questions to ponder:

How would you evaluate the behaviour of the agents in this case from the ethical perspective? Do you think that Mrs. Fiona, the sponsor and the provider of health services, and Mrs. Fiona's relatives acted ethically? Why?

See Article 33 of the Declaration of Helsinki. Do you find it applicable to this case? Do you think said provision is right from the ethical perspective?

Do you think that the action brought by Mrs. Fiona's relatives would be successful?

#### 4. CASE 4 – FINANCIAL INCENTIVES AND THE NATURE OF HUMAN EMBRYOS

Mr. and Mrs. Johnson successfully undergo an IVF treatment resulting in the birth of two healthy children. Several embryos were not used for the implantation in Mrs. Johnson's body and remain cryopreserved in the IVF medical facility. After ten years, Mr. and Mrs. Johnson are asked by the provider of health services to give their permission to the use of their surplus embryos in embryo-destructive research. Even though Mr. and Mrs. Johnson were informed about this possibility before the IVF treatment, they are now unsure about it and do not seem to be willing to grant the consent. Since the researchers need to obtain enough embryos in a short time, the leading physician at the laboratory, Dr. Phillips, invites Mr. and Mrs. Johnson to a private consultation. When they meet in his office, Dr. Phillips offers the Johnsons a rather nice sum of money for their consent. Dr. Phillips asks the Johnsons not to tell anyone about his offer but explains that it does not violate international law (namely Article 21 of the Convention on Biomedicine) since embryos are not human body or its parts. Mr. and Mrs. Johnson only need a short time for thinking about how much their nine-year-old children want to go on a summer holiday this year, and accept the deal.

Questions to ponder:

How would you evaluate the behaviour of the agents in this case (Dr. Phillips, Mr. and Mrs. Johnson) from the ethical perspective? Why?

Try to find out when and under what circumstances are financial incentives for research participants legal. Do you think the current legal regulation and practice is ethically right?

The exact nature of a human embryo which exists outside of the woman's body is not entirely clear from the legal perspective. What do you think its nature should be? (E.g., it could be a part of someone's body, a person recognised by the law, a thing in the legal sense, etc.)

## 9. END OF LIFE

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During this Session, we are going to deal with what are known as end-of-life decisions: euthanasia, assisted suicide, switching off a mechanic support of life functions, palliative/terminal sedation etc.

First of all, we are going to spend some time on terminology and on – as I call it -traditional systematic of euthanasia. I want to make clear that the term euthanasia is often used in a quite confusing way, which also leads to very unconvincing results of surveys conducted in order to find out whether people would like to have euthanasia legalised/decriminalised.

Then you are going to be provided with a brief summary of law on euthanasia, so we could have a closer look at the famous Dutch euthanasia law which indeed has served as an example and has been copied by some other countries. We are going to analyse it critically and point out the most problematic aspect of it, in comparison to other legislation.

Last but not least we are going to discuss the slippery slope effect in the highly controversial case of a Belgian prisoner.

The main idea of this session is to provide you with sufficient information in order to be able to evaluate current legal provisions on end-of-life decisions in the Czech Republic and orientate yourself in the never ending discussions regarding legalisation of euthanasia in the Czech Republic.

### 1. TERMINOLOGY

Type of action	Euthanasia? Y/N	Acceptable? Y/N
Obeying a DNR order		
Prescription of a lethal dose for a patient who wants to commit suicide		
Life termination provided to a terminally ill and unbearably suffering patient on his/her own repeated request.		
Increasing dose of pain killers up the point when they kill the patient		
Life termination of a patient in a coma		
Switching off a ventilator		

### 2. LIFE TERMINATION ON REQUEST AND ASSISTED SUICIDE

Euthanasia, i.e. life termination upon the request of an unbearably suffering patient by means of a lethal dose of a drug provided to the patient by another person, is considered a criminal offence<sup>42</sup> in most countries in the world. Therefore, the euthanasia laws as

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<sup>42</sup> I.e. murder, manslaughter or other offence against life (e.g. killing on request).

enacted in the Netherlands<sup>43</sup>, Belgium,<sup>44</sup> Luxemburg<sup>45</sup> and Spain, clearly still represent a highly controversial exception.

Assisted suicide, if provided by a doctor, consists mainly in prescribing a lethal dose of a drug, which is afterwards used by the patient themselves. So-called physician assisted suicide (PAS) has been under certain conditions proclaimed not to be a crime in the Netherlands<sup>46</sup>, Luxembourg<sup>47</sup> and some US states (including Oregon<sup>48</sup>, Washington<sup>49</sup>, Montana<sup>50</sup>, California<sup>51</sup> etc.). However, under some circumstances, assisted suicide might neither be prosecuted in Switzerland<sup>52</sup>, Germany<sup>53</sup> and Great Britain<sup>54</sup>. In the Netherlands, Luxemburg and in specific states of the USA the law applies only if a doctor assists in the suicide of a seriously ill patient in an advanced (if not even terminal) stage of their illness.

In the light of the latest changes to the Belgian Act on Euthanasia, under which it is now possible to provide euthanasia to all minor patients regardless of their age if they are mature enough to understand the meaning of their request for euthanasia, this short text offers a brief overview of the most recent laws on euthanasia and assisted suicide in those countries where they have been conditionally decriminalised. Concerning other end-of-life decisions, such as withdrawal of a ventilator or palliative sedation, these will not be discussed in this paper. This is because these end-of-life decisions do not fulfil the definition of euthanasia which was referred to above.

## 2.1 THE NETHERLANDS

In the Netherlands, the Termination of Life on Request and Assisted Suicide Act (Review Procedures) (further referred to as Termination of Life Act) came into effect on 1 April 2002. The Termination of Life Act lays down the conditions (the so-called criteria of proper care) under which a doctor does not commit the offence of killing on request and/or assisted suicide.

At this point, it should be emphasised that the process of decriminalising euthanasia already started in the 1980s via Dutch case law (among other cases, the key decision was in *Re Dr. Schoonheim*<sup>55</sup>); the new Termination of Life Act should therefore not be understood as a crucial legislative breakthrough.

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<sup>43</sup> *Wet toetsing levensbeëindiging op verzoek en hulp bij zelfdoding together with S. 293 of the Dutch Criminal Code.*

<sup>44</sup> *Loi relatif à l'euthanasie suicide.*

<sup>45</sup> *L'euthanasie et l'assistance au suicide together with Art. 397-1 of the Luxembourg Criminal Code.*

<sup>46</sup> *Wet toetsing levensbeëindiging op verzoek en hulp bij zelfdoding together with S. 294 of Criminal Code.*

<sup>47</sup> *L'euthanasie et l'assistance au suicide together with Art. 397-1 of the Luxembourg Criminal Code.*

<sup>48</sup> *Death with Dignity Act 1997.*

<sup>49</sup> *Death with Dignity Act 2008.*

<sup>50</sup> *Baxter v. Montana, Rozhodnutí Nejvyššího soudu Montany (Supreme Court of Montana) ze dne 31.12.2009.*

<sup>51</sup> <http://edition.cnn.com/2015/10/05/us/california-assisted-dying-legislation/>

<sup>52</sup> *Art. 115 of the Swiss Criminal Code.*

<sup>53</sup> *The case of Hackethal. OLG. München NJW 1987, 2940.*

<sup>54</sup> *R (on the application of Purdy) v Director of Public Prosecutions [2009] UKHL 45.*

<sup>55</sup> *Decision Alkmaar from 21.10.1986 in the case of Dr. Schoonheim.*

According to the so-called criteria of proper care as they are defined by the Termination of Life Act<sup>56</sup>,

- the attending doctor must come to the conclusion that the patient requests life termination (euthanasia) or assisted suicide freely and on their own accord and that the request of the patient is well considered,
- the attending doctor must be convinced that the patient is suffering unbearably and there is no prospect of improvement,
- the patient must be fully informed of his state of health, prognosis, and possible alternatives (incl. palliative care),
- the condition of the patient is consulted with another independent doctor who confirms the fulfilment of all above mentioned requirements,
- life termination and/or assisted suicide must be provided in a proper way (i.e. among other requirements, with a specific amount of a precisely specified drug),
- the patient must be older than 12; patients between 12 and 16 years of age could only be provided with euthanasia or assisted suicide if their parents give consent to it in advance. If the patient is over 16, no additional parental consent is required. However, the parents must be informed about the request of the patient in advance.

The request for life termination may also be expressed in the form of advanced decisions; with respect to all the above-mentioned conditions it is not possible to provide euthanasia to a patient in a coma (the patient is not suffering unbearably).

Life termination upon request, as well as assisted suicide, must be reported by the attending doctor to a control commission. The control commission is then supposed to decide whether the criteria of proper care have been fulfilled by the attending doctor; this decision is reached after consideration of the protocol performed by the attending doctor, or as the case may also be, after taking into account other proof. If the control commission comes to the conclusion that the criteria have not been fulfilled by the attending doctor, the case is forwarded to the prosecution. However, this kind of situation does not occur very often – in 2008, there were 2331 cases reported by the attending doctors, out of which only 10 were forwarded to the prosecution<sup>57</sup>, and in 2009 there were 9 cases forwarded out of 2636 cases reported<sup>58</sup> etc. Nevertheless, these statistics cannot be interpreted to mean that the Dutch practice of euthanasia is without any serious problems.<sup>59</sup>

The Termination of Life Act is not to be applied in so-called standard medical decisions, i.e. in cases of withdrawal or withholding of futile healthcare, withdrawal of or withholding treatment which was not consented to by the patient, and palliative sedation.<sup>60</sup> According

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<sup>56</sup> S. 1–4 of the Termination of Life Act.

<sup>57</sup> Regional euthanasia review committees. Annual report. 2008, on p. 33. Available on the internet on the webpage [http://www.euthanasiecommissie.nl/Images/Jaarverslag%202008%20Engels\\_tcm52-27032.pdf](http://www.euthanasiecommissie.nl/Images/Jaarverslag%202008%20Engels_tcm52-27032.pdf).

<sup>58</sup> Regional euthanasia review committees. Annual report. 2009, on p. 3.

<sup>59</sup> See more details in.: Peterková, H.: Role lékaře při ukončení života na žádost a pomoci při sebevraždě. In Ptáček, Radek; Bartůněk, Petr (eds.) Eutanazie – pro a proti. 1. vyd., Praha: Grada, 2012, s. 138–144. ISBN 978-80-247-4659-3.

<sup>60</sup> Griffiths, J., Weyers, H., Adams, M.: *Euthanasia and the Law in Europe*, Hart, Oxford, 2008, p. 91.

to some commentators, this dichotomy results in falsifying medical records and circumvention of the duty of doctors to report euthanasia and assisted suicide.



## 2.2 BELGIUM

The Belgian Act on Euthanasia came into effect on 28 May 2002<sup>61</sup> and is designed in the same manner as the Dutch Termination of Life Act, although it is much more detailed. The main difference between the Belgian and Dutch law on euthanasia could be briefly described as follows:

The Belgian Act on Euthanasia decriminalises only life termination upon request, thus it does not decriminalise assisted suicide.

The Belgian Act on Euthanasia distinguishes the criteria of proper care depending on whether the patient is in the terminal stage of their illness or not yet.

The Belgian Act on Euthanasia does not require a certain age of a patient in order to provide the patient with euthanasia, if other statutory conditions are met.<sup>62</sup>

## 2.3 LUXEMBOURG

In Luxembourg, the Act on Euthanasia and Assisted Suicide was adopted on 16 March 2009 and is in principle similar to the Dutch Termination of Life Act. Together with a euthanasia law, a law on palliative care was also adopted.<sup>63</sup>

## 2.4 SWITZERLAND

In Switzerland, the impunity of certain kinds of assisted suicide is concluded with regards to the legal definition of the criminal offence of assisted suicide. According to Article 115 of the Swiss Criminal Code, assisted suicide is committed if there is an egoistic motive of the offender: Therefore, if there is no egoistic motive of the assistant to suicide, there is no criminal liability to be imposed.<sup>64</sup>

There are several so-called right-to-die organisations (Sterbehilfeorganisationen or rather Suizidhilfeorganisationen<sup>65</sup>) which offer institutionalised assisted suicide, among other services such as consulting regarding advanced directives. Some of the organisations (Dignitas, EX-International) also provide assisted suicide to foreign patients, if the patients are members of the organisation. Beside the absence of an egoistic motive, the Swiss practice has laid down some additional conditions to be fulfilled if the assisted suicide is institutionalised and with the participation of a doctor (legal capacity of the patient,

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<sup>61</sup> Loi relative à l'euthanasie. Law of 28 May 2002 on Euthanasia, amended by the Law of 13 February 2014 – Consolidated version. The consolidated version is available on the website <http://eol.law.dal.ca/wp-content/uploads/2014/02/Law-of-28-May-2002-on-Euthanasia-as-amended-by-the-Law-of-13-February-2014.pdf>.

<sup>62</sup> 1. The minor with the capacity of discernment is in a medically futile condition of constant and unbearable physical suffering that cannot be alleviated and that will result in death in the short term, and that results from a serious and incurable disorder caused by illness or accident. (S.1 of the Act on Euthanasia)  
2. when the patient is an unemancipated minor, consult, in addition, a child psychiatrist or a psychologist, and inform him about the reasons for this consultation.... (S. 2 Para 7 of the Act on Euthanasia).

<sup>63</sup> Both Acts were as “législation réglementant les soins palliatifs ainsi que l'euthanasie et l'assistance au suicide” published in Coll. Au Mémorial A 2009 n° 46.

<sup>64</sup> Art. 115 of the Swiss Criminal Code

<sup>65</sup> Exit (Deutsche Schweiz), Exit – Association pour le droit de mourir en dignité, Dignitas – Menschenwürdig leben – Menschenwürdig sterben, EX- International, Verein SuizidHilfe. Besides institutionalised assisted suicide, assisted suicide provided by individuals is also available in Switzerland. In: Venetz, P.: Suizidhilfeorganisationen und Strafrecht, LBR Band 28, Schulthess 2008, on p. 16–47.



actual ability of the patient to decide about their end of life, hopeless prognosis, unbearable suffering, and others).<sup>66</sup> There is no right to assisted suicide recognised by Swiss law in the cases of patients suffering from a mental disorder (bipolar affective disorder).<sup>67</sup> However, the Swiss practice of assisted suicide has recently been subjected to the scrutiny of the European Court of Human Rights which claims that there is an unacceptable legal uncertainty concerning the conditions under which a patient could be prescribed a lethal drug used for assisted suicide (pentobarbital).<sup>68</sup>

## 2.5 OREGON

In Oregon, it is required by law that the suicide may only be assisted by a doctor. A patient requiring assisted suicide must be terminally ill, i.e. with the prognosis of life expectation shorter than 6 months, and must ask for assisted suicide three times, of which one request must be in writing. The request must be seriously intended and is to be reviewed by two doctors. There must be an interval of at least 15 days between the request and prescribing the lethal drug. The Oregon Death with Dignity Act has served as an example for several other states of the USA.<sup>69</sup>

## 2.6 TASKS REGARDING LIFE TERMINATION ON REQUEST AND ASSISTED SUICIDE

- A. What is the main difference between life termination on request and assisted suicide?
- B. What would you think of a legal system in which life termination on request is not a crime, but assisted suicide is?
- C. What might be the consequence if a country only punishes life termination on request, but not assisted suicide?

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<sup>66</sup> E.g. Informations-Broschüre available on the website:

[http://www.dignitas.ch/index.php?option=com\\_content&view=article&id=22&Itemid=62&lang=de](http://www.dignitas.ch/index.php?option=com_content&view=article&id=22&Itemid=62&lang=de).

<sup>67</sup> Decision of the ECHR Haas v. Switzerland.

<sup>68</sup> Decision of the ECHR Gross v. Switzerland.

<sup>69</sup> Based on the text published as PETERKOVÁ, Helena. Právní úprava euthanasie a pomoci při sebevraždě [online]. Anesteziologie, resuscitace a intenzivní medicína, 2014, 61(2), s. 15-20.

### 3. TERMINATION OF LIFE AND ASSISTED SUICIDE (REVIEW PROCEDURE) ACT

#### Article 2

1. The requirements of due care referred to in Article 293 second paragraph Penal Code mean that the physician:
  - a. holds the conviction that the request by the patient was voluntary and well-considered,
  - b. holds the conviction that the patient's suffering was lasting and unbearable,
  - c. has informed the patient about the situation he was in and about his prospects,
  - d. and the patient holds the conviction that there was no other reasonable solution for the situation he was in,
  - e. has consulted at least one other, independent physician who has seen the patient and has given his written opinion on the requirements of due care, referred to in parts a - d, and
  - f. has terminated a life or assisted in a suicide with due care.
2. If the patient aged sixteen years or older is no longer capable of expressing his will, but prior to reaching this condition was deemed to have a reasonable understanding of his interests and has made a written statement containing a request for termination of life, the physician may carry out this request. The requirements of due care, referred to in the first paragraph, apply *mutatis mutandis*.
3. If the minor patient has attained an age between sixteen and eighteen years and may be deemed to have a reasonable understanding of his interests, the physician may carry out the patient's request for termination of life or assisted suicide, after the parent or the parents exercising parental authority and/or his guardian have been involved in the decision process.
4. If the minor patient is aged between twelve and sixteen years and may be deemed to have a reasonable understanding of his interests, the physician may carry out the patient's request, provided always that the parent or the parents exercising parental authority and/or his guardian agree with the termination of life or the assisted suicide. The second paragraph applies *mutatis mutandis*.

...

Article 293 reads:

#### Article 293

1. A person who terminates the life of another person at that other person's express and earnest request is liable to a term of imprisonment of not more than twelve years or a fine of the fifth category.
2. The offence referred to in the first paragraph shall not be punishable if it has been committed by a physician who has met the requirements of due care as referred to in Article 2 of the Termination of Life on Request and Assisted Suicide (Review Procedures) Act and who informs the municipal autopsyist of this in accordance with Article 7 second paragraph of the Burial and Cremation Act.

B

Article 294 reads:

#### Article 294

1. A person who intentionally incites another to commit suicide, is liable to a term of imprisonment of not more than three years or a fine of the fourth category, where the suicide ensues.
2. A person who intentionally assists in the suicide of another or procures for that other person the means to commit suicide, is liable to a term of imprisonment of not more than three years or a fine of the fourth category, where the suicide ensues. Article 293 second paragraph applies *mutatis mutandis*.

### **3.1 TASKS REGARDING THE ACT**

- A. What is the most important criterion? Why?
- B. Should minors be allowed to decide about terminating their life?
- C. What is neonatal euthanasia?
- D. What Act is meant to be changed by new versions of Art. 293 and 294?
- E. Explain the difference between legalisation and decriminalisation. Which one describes the situation in Netherlands?

### **4. BELGIAN PRACTICE OF EUTHANASIA**

A murderer serving a life sentence in a Belgian jail asked to be allowed to die by lethal injection....

The case raises an interesting question - whether prisoners serving long jail terms should be allowed to choose medically assisted death. In Belgium, euthanasia is available for the terminally ill, and also for those who wish to end psychological suffering.<sup>70</sup>

### **TASKS REGARDING THE BELGIAN PRACTICE OF EUTHANASIA**

- A. Explain what a slippery slope argument is.
- B. Should life termination on request and/or assisted suicide law in the Czech Republic change? Explain your position.

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<sup>70</sup> Available on <https://www.bbc.com/news/magazine-30708585> (accessed in February 2021).

## 10. ETHICS CONSULTATION SERVICES

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During this session, we are going to consider real case studies from hospitals. We will consider these case studies from the perspective of a professional in ethics consultation services, so you can get know the methods behind solving a case better.

In order to get some theoretical background, please have a look at the text below.

### 1. THEORY OF ETHICS CONSULTATION SERVICES

The first signs of a value (ethical) conflict are often (negative) emotions such as fear, uncertainty, tension, anger, or in general the development of negative emotions – either the loud ones or the silent ones (aggressive silence). These negative emotions warn us that an interest of some participants of the conflict is in danger.

In that case, the participant might be found willing to take a hard attitude and be ready to fight. This situation is called a position of a participant of a conflict and is actually a defensive strategy of a concrete participant of the conflict.

One often argues his/her position by referring to the law and to people's entitlements. We want to justify our interests with objective claims, and we perceive as objective the social, moral, or legal norms and rights.

Positions are linked with the interest of the participants of the conflict, which are the reasons and motives for everything that we do, why we fight, give up or win. Sometimes, the interests are not unique to only one participant of the conflict, as the interests of the participants of the conflict may overlap and be shared by more participants. This overlap can be a base for building a consensus in the conflict.

To understand how dealing with various interests works, we need to bear in mind that often they are so deep within a person, that he/she does not directly verbalise them; however, they are so important that if they are endangered people react with emotions.

The mediator's task is to help the participants to verbalise these interests peacefully, in a way that the counterpart does not have to withdraw into a defensive position and to "defend" his/her interests by objectively accepted norms.

Interests are:

- Substantive: goods, time, money and other resources.
- Psychological: respect, safety, face-saving.
- Procedural: are focused on being heard and a feeling that the decision was made fairly.

For detecting an arising conflict, which has a potential to grow and to possibly become a legal danger, it is eminent to have the ability of empathy, i.e. the ability to read both one's own emotions as well as the emotions of other participants of the conflict, to not be afraid to name the emotions, and to express oneself with respect.

Generally, the earlier the conflict is detected, the higher the chance for an acceptable solution. First, we should name the emotions. Whilst doing so, we do not escalate

the conflict, but we demonstrate that we hear the participants and that we take them seriously. Showing respect has the power to remove the conflict. Only later we point out what disturbs us and we criticise it.

Consensual agreement as a part of the conflict resolution

During the meeting we try to name the elements of the conflict, where there is (could be) a consensual agreement, as far as the further care of the patient is concerned.

We find out whether this consensus is really acceptable for the participants from an unanimous verbal or nonverbal affirmation.

If there is only a partial consensus, we name what is really common in the solution that we are searching for, and we propose a further meeting in a time interval appropriate for the real clinical situation of the patient.

In this second meeting, we can find a new, modified solution, based on the effectiveness of the previous solution and the dynamics of the development of the disease itself.

“Principled resolution” as a criterion and a structure of a solution of a value (ethical) conflict

Principled resolution is a plan that falls within clearly accepted ethical principles, legal stipulations, and oral rules, defined by an ethical discourse, the legislation and the court. It facilitates a clear plan for future interventions, because we do not want to stand in front of a court every day, and neither do we want to be in constant conflict with the society. (Framework Beauchamp and Childress, human rights ethics – right for corporal integrity e. g.).

By solving the case we answer the principal questions only indirectly. When solving a concrete case, we for instance do not solve the question whether euthanasia should be decriminalised in the Czech Republic.

It is possible to verify what is the relationship of the consensually found solution to the ethical principle by some analytical methods, for example:

- The Four Boxes Approach by Jonsen, Siegler, Winslade,
- The Nijmegen Method for resolving ethically complicated cases,
- The CASES analysis of IntegratedEthics Program.

The conclusions of these could be completed with casuistry, as a comparative method, with which we compare similar cases.

For a more profound understanding of the conflict, when we need to name the ethical problem clearer, we can use the Hermeneutical Method of the Case Resolving.

Within the use of the “principled resolution”, it is possible to “just” listen to the participants of the conflict and to perceive the principles of autonomy, beneficence, nonmaleficence and justice only generally and more intuitively, rather than to “just” rationally reflect to what extent the arising solution is in conformity with these principles.

Similarly, we can use the principles of medical law.

# APPENDIX

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## SELECTED PROVISIONS OF ACT ON HEALTHCARE SERVICES

### Act No. 372/2011 Coll., on health services and on conditions of their provision

of the 6<sup>th</sup> November 2011

#### (The Health Services Act)

(unofficial translation of selected legal provisions, for study purposes only!) <sup>71</sup>

....

#### STATUS OF THE PATIENT AND OTHER PERSONS IN CONNECTION WITH THE PROVISION OF HEALTHCARE SERVICES

#### RIGHTS AND OBLIGATIONS OF THE PATIENT AND OTHER PERSONS

##### Rights of the patient

##### § 28

(1) Health services may be provided to the patient only with his/her free and informed consent, unless otherwise provided in this Act.

(2) The patient shall be entitled to the provision of health services at the appropriate professional level.

(3) Whilst being provided with health services, the patient is also entitled

(a) to respect, to being treated with dignity, to courtesy and respect for privacy whilst being provided with health services, in accordance with the nature of health services,

(b) to choose a provider of health services who is authorised to provide health services that meet the patient's health needs, and a health facility, unless otherwise provided in this Act or in other legislation,

(c) to request consultancy services from a different provider or a healthcare professional than the current ones; this shall not apply in the case of urgent care or in the case of custody, imprisonment or detention,

d) to be acquainted with the internal rules of the inpatient or one-day care healthcare facility (hereinafter referred to as the "Internal Rules"),

e) to

1. the continuous presence of a legal guardian or a person appointed by a legal guardian, a foster parent or another person to whom the patient has been entrusted, by decision of the court or of another body, if the patient is a minor,

2. the continuous presence of a caregiver or a person appointed by a caregiver, if the patient is a person whose legal capacity is limited so that s/he is not competent to assess the provision of health services, or the consequences of their provision (hereinafter referred to as "the patient with a limited legal capacity"),

3. the presence of a next of kin<sup>72</sup> or a person designated by the patient,

in accordance with other legislation and internal rules, and provided that the presence of such persons does not impair the provision of health services; this shall not apply to persons in custody, imprisonment or security detention; this provision, however, does not affect S. 47 (2) b) of this Act.

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<sup>71</sup> Available in June 2020 on: [http://www.mzcr.cz/Cizinci/dokumenty/act-no372/2011-collon-health-services-and-on-conditions-of-their-provision-18562\\_4129\\_23.html](http://www.mzcr.cz/Cizinci/dokumenty/act-no372/2011-collon-health-services-and-on-conditions-of-their-provision-18562_4129_23.html), with changes by HKVB (however, the act is not accessible online anymore). As there is no English version of the Act available, the crucial provisions needed for the course are also presented in the Reading Material.

<sup>72</sup> Originally: "close relative" – what is the difference?

f) to be informed in advance about the price of health services which are not covered or partially covered by public health insurance and as well about the method of payment, if the health of the patient enables such information to be provided,

g) to know the name or names of the healthcare workers and other professionals directly involved in providing the healthcare services, as well as of the persons preparing themselves for their future medical profession, which are at present providing health services or engage in activities that are part of the curriculum,

h) to reject the presence of persons who are not directly providing the healthcare services to patient ...

i) to receive visitors in a medical facility, with regard to their health status and in accordance with the internal rules and in a manner which does not infringe the rights of other patients, unless otherwise stated by the law,

j) to receive pastoral care and spiritual support from churches and religious communities registered in the Czech Republic or from persons involved in religious activities ... within the medical facilities in accordance with the internal rules and in a manner which does not infringe the rights other patients with regard to the health of the patient ...,

k) to be provided with healthcare services in the least restrictive environment while ensuring the quality and safety of healthcare services.

(4) Patients with limited legal capacity and minor patients are entitled to require not to be provided with the healthcare in the presence of a person acc. to para 3 point e) if the patient states that he is mistreated or abused by the person. In this case, the next procedure is in accordance with s. § 35 para 5.

...

## **§ 29**

(1) ...

(2) Choice of provider and medical facility does not apply to

a) emergency medical services and the provider to which the patient is transported by emergency medical services,

b) occupational medical services,

c) compulsory isolation, quarantine or protective treatment,

d) persons placed in police cells set up at the police department of the Czech Republic; ...

e) persons in detention, imprisonment, preventive detention ...

...

Information about the patient's condition and the proposed health services

## **§ 31**

(1) The provider is obliged to

a) ensure that the patient was understandably and to a sufficient extent informed about the patient's health and about proposed individual treatments and all relevant changes (further referred to as "health information"),

b) allow the patient or a person designated by the patient to ask additional questions related to the patient's health medical condition and the proposed health services, which must be clearly answered,

(2) Health information referred to in paragraph 1 shall contain information on

a) the cause and origin of the disease, if known, the stage and the expected development,

b) the purpose, nature, the expected benefits, potential risks and consequences of proposed health services, including individual medical procedures,

c) other options for providing healthcare services, their suitability, benefits and risks for the patient,

- d) other necessary treatment,
  - e) the limitations and recommendations concerning the lifestyle of the patient with regards to the patient's health
  - f) the option
1. to renounce the right to health information according to s. 32,
  2. to designate the persons in accordance with s. 32 and 33 or to prohibit a disclosure of health information in accordance with s. 33.

Health information is communicated to the patient upon admission to healthcare and then always when ... appropriate.

(3) Health information is provided by the attending healthcare worker who is qualified to provide healthcare services to which is the information related to; the health information is to be written down in the patient's medical documentation by the attending healthcare worker.

(4) The health information is not provided to the patient, if – because of the health condition of the patient - the patient is not able to perceive the health information.

(5) Regarding a minor patient or a patient with limited legal capacity, the legal representative or guardian of the patient have the right to health information of the patient as well as the right to ask further questions about the health of the patient.

(6) The healthcare provider is authorized to disclose the health information of the patient to the persons who will take care of the patient, in order to ensure the appropriate care of the patient or the protection of the health of those persons, if this disclosure is required by the health of the patient or the nature of the illness of the patient.

## § 32

(1) The patient may renounce the right to be provided with the health information or the patient may designate a person who is entitled to be provided the health information instead of the patient. The renounce or designation is to be written down in the medical documentation of the patient ... The renouncement is not taken into account if the patient is suffering from infectious disease or other illness in connection with which the health or life of others may be endangered.

(2) Unfavourable health information about diagnosis or prognosis of the patient may be withheld - to the extent which is necessary and for a necessary time period only - if there is a reasonable assumption that its disclosure may cause serious harm to the patient, unless

- a) the information about a certain disease or a predisposition of the patient towards the disease is the only way to enable the patient to take preventive measures or to undergo early treatment,
- b) the patient's health poses a risk to his surroundings,
- c) the patient asks specifically for truthful and accurate information in order to take care of private matters.

(3) The provider may - to the extent which is necessary - withhold the health information about a minor patient from the legal guardian, foster parent or other caregiver of the patient in case of a suspicion that the person concerned misuses or abuses the child or poses a threat to the healthy development of the patient and if it can be assumed that providing this information could jeopardize the patient. Similar procedure will be applied in a case of a patient with limited legal capacity.

## § 33

(1) During the admission to the healthcare, the patient may designate persons who are entitled to obtain the patient's health information. At the same time, the patient may decide whether these persons are entitled to access to the medical documentation of the patient (...) and whether they are entitled to take notes and copies of the medical documentation. The patient may designate persons who are – according to the conditions under S. 34 para 7 - entitled to express their consent or refusal to the healthcare. The designation or prohibition against the disclosure of health information could be communicated as well as withdrawn by the patient at any time after the admission. The designation and prohibition against disclosure of health



information is a part of medical documentation. The medical documentation consists as well of a record about the patient's instruction of how the information may be disclosed.

(2) The prohibition against the disclosure of health information does not apply if the information may be disclosed without the consent of the patient according to this Act or other legal provisions.

(3) If the patient is not able – because of their health condition - to designate the persons according to Para 1, next of kin of the patient are entitled both to obtain the health information regarding the actual health condition of the patient and to take notes and copies of the patient's medical documentation. If there is a prohibition against the disclosure of the health information to a particular person, this person may only be provided with the health information - to the extent which is necessary - if it is in the interest of the protection of the health of the person or other persons.

(4) The next of kin of a deceased patient or other persons designated by the patient have the right to patient's health information and information regarding the results of the autopsy, if carried out, including the right both to access to medical documentation (...) and to take notes and copies of the medical documentation. If the patient prohibited the disclosure of the health information to a particular person belonging to the next of kin, this person may only be provided with the health information - to the extent which is necessary - if it is in the interest of the protection of the health of the person or other persons.

(5) Persons who came into contact with a patient have the right to the patient's health information - to the extent necessary – if the information is relevant for the protection of their health.

Healthcare services provided with the consent of the patient

### § 34

(1) Consent to healthcare services (further referred to as “the consent”) is considered

a) free, if it is given without any coercion,

b) informed, if the patient is provided with the information according to S. 31 before consenting to the healthcare service; the consent is considered informed as well in case that the patient has renounced the right to health information according to S. 32 Para 1.

(2) The consent is required to be put in writing if it is required by other legal provisions or if it is set – with regard to the nature of the healthcare service concerned – by the healthcare provider. Consent to hospitalization must always be in writing. On request, the patient is provided with a copy of the written consent.

(3) The patient who has obtained health information or who has renounced the right to health information and who refuses to consent to healthcare services, unless the healthcare services can be provided without the consent of the patient, is repeatedly informed about their health condition to the extent which clarifies that without the healthcare services the patient's health or life may be endangered. If the patient still refuses to consent, he puts the refusal into writing.

(4) The patient may withdraw the consent to healthcare. The withdrawal of the consent is not effective if medical intervention has already started and its interruption may cause serious harm to health or may endanger the life of the patient.

(5) A written consent, a written withdrawal of the consent, or a record of the withdrawal of the consent, if the patient refuses to put the refusal into writing, is a part of medical documentation of the patient. If the patient refuses to sign the record according to the first sentence, this circumstance is to be recorded within the medical documentation of the patient; the record is to be signed by a healthcare worker and a witness.

(6) If the patient's health condition does not allow the patient to express a consent to the healthcare service, a withdrawal of the consent or a refusal of the treatment, the healthcare worker will record the undoubtable expression of patient's will as well as the way in which the patient has expressed their will and the health reasons which hinder the patient from expression in a required way; the record is to be signed by the healthcare worker and a witness.

(7) If the patient cannot – because of his health condition – give a consent to a healthcare service, unless the health service can be provided without consent, a consent of a person designated by the patient according to S. 33 Para 1 is required; if there is not such a person or the person is unreachable, the consent of a spouse

or

a registered partner is required; if there is not such a person or the person is unreachable, the consent of a parent is required; if there is not such a person or the person is unreachable, a consent of another legally competent next of kin is required if such a person is known.

### § 35

(1) Whilst providing healthcare services to a minor patient, the opinion of the minor patient on being provided with the healthcare services is to be found out if this is appropriate for the intellectual and volitional maturity of the minor patient. The opinion of the minor patient must be taken into consideration as a factor which increases proportionally to the age and degree of intellectual and volitional maturity of the minor patient. The legal provisions on legal capacity are to be applied to the informed consent expressed by a minor patient with the specification that healthcare services may be provided to the patient on the basis of the consent of the minor patient, if the consent is appropriate for the intellectual and volitional maturity of the age of the minor patient. This rule does not apply for healthcare services which may be provided without consent.

(2) The fact that the healthcare services were provided on the basis of the consent of a minor patient does not hinder the healthcare worker from disclosure of the patient's health information to their legal representative.

(3) In the case of healthcare services which consist of providing

- a) emergency care, which is care according to S. 38 Para 4, or
- b) acute care,

if the consent of a legal representative of the patient cannot be obtained without undue delay, the decision to provide the patient with healthcare services may be taken by a healthcare worker. This rule does not apply if the healthcare services may be provided according to Para 1 on the basis of the consent of the minor patient.

(4) In the case of a patient with limited legal capacity, Para 1 to 3 are to be applied mutatis mutandis in the sense that the age of the patient is not to be taken into consideration.

(5) In the case of a patient according to S. 28 Para 4, the healthcare provider excludes the presence of the persons mentioned in S. 28 Para 3 point E) by providing the healthcare, if there is a suspicion that the patient is abused or tortured or the healthy development of the patient is threatened and the purpose of the healthcare services is to eliminate such a suspicion.

### § 36

Previously expressed wishes

(1) The patient may, in case of anticipating a state of health which will not allow the patient to give an informed consent with or refusal of the provision of health services and the way they are provided, express his or her own will (hereinafter referred to as "previously expressed wish").

(2) The provider will take into account previously expressed wishes of the patient, if it is available, and under the condition that at the time of providing the above mentioned health services the predictable situations occurred to which the previously expressed wish applies, and the patient is in such a state of health that he or she is not able to express actual informed consent or refusal. Only such a previously expressed wish is to be respected that was made on the basis of written information regarding the consequences of patient's decision, provided to the patient by the patient's GP or another physician with a specialisation to which the previously expressed wish is related.

(3) The previously expressed wish must be in writing with an officially verified signature of the patient. The written information pursuant to paragraph 2 must be included within the previously expressed wish.

(4) The patient may express his or her previously expressed wish also during the patient intake process or anytime during hospitalization, for the provision of health services provided by this provider. Such a previously expressed wish shall be written down in the medical records of the patient; the record shall be signed by the patient, healthcare worker and a witness; in this case it shall not be proceeded in accordance with paragraph 3.

(5) A previously expressed wish

a) does not need to be followed if, since the time it was expressed, there has been such development in the provision of healthcare services, to which this wish relates, that it can be reasonably assumed that the patient would have agreed to their provision; ...

b) may not be followed if it encourages such practices which result in an active cause of death,

c) may not be followed if its fulfilment could endanger other persons,

d) may not be followed if certain medical procedures have already been started because the previously expressed wish was not available for the healthcare provider at the relevant moment and the interruption of these procedures would lead to an active cause of death.

(6) Previously expressed wishes do not apply in the case of minors or patients with limited legal capacity.

...

### **§ 38**

(1) Without the consent of the patient concerned, the patient may be hospitalized if

a)

1. the patient shall undergo a protective inpatient treatment according to a legally effective court decision

2. isolation, quarantine or treatment under the Act on the Protection of Public Health was ordered

3. a medical examination under the Criminal Procedure Act or the Act on Special Court Procedures was ordered,

b) the patient threatens immediately and seriously themselves or their surroundings and shows signs of mental disorders or suffers from mental disorder or is under the effect of addictive substance, if the threat for the patient or their surroundings cannot be averted otherwise.

c) the health condition of the patient requires emergency care and makes it impossible for the patient to consent.

(2) A minor patient or a patient with limited legal capacity may without a consent of the patient's legal representative or guardian as well be hospitalized in case of suspected abuse, torture or neglect.

(3) A patient may without their consent only be provided with emergency care, if

a) the health condition of the patient does not allow the patient to consent; this does not affect the patient's previously expressed wishes according to S. 36,

b) a serious mental disorder shall be treated which - if untreated - can result in serious damage to the health of the patient.

(4) A minor patient or a patient with limited legal capacity may without their consent only be provided with emergency care

a) in cases according to Para 3 point b) or

b) consisting of healthcare services necessary to save life or to prevent a serious harm.

(5) A minor patient or a patient with limited legal capacity can be provided with emergency care without a consent of their legal representative or guardian if there is suspicion of abuse or neglect.

(6) The healthcare provider is obliged to inform about the hospitalization according to Para 1 point b) or c) the person designated under S. 33, unless there is not such a person, to inform any of the next of kin, or the person from the same household, or patient's legal representative, if known. If there is no person under the first sentence known to the provider or this person is not reachable, the Police of the Czech Republic is to be informed.

(7) Without the consent, other medical services may be provided if stated by the Act on the Protection of Public Health.

### **§ 39**

(1) To restrain the free movement of patients whilst providing the healthcare services, the following measures (further referred to as "restraints") may be used:

- a) grips by healthcare staff or other persons designated by the healthcare provider,
- b) restraining of the movement of the patient with protective bands or courts,
- c) placing the patient in a netted bed,
- d) placing the patient in a room designed for safe movement,
- e) protective jacket or vest to prevent movement of the upper limbs of the patient,
- f) psychopharmaca, or other drugs administered parenterally, that are appropriate to restrict the free movement of patients in the provision of health services, unless it is a treatment on the request of the patient or a systematic treatment of psychiatric disorders, or
- g) a combination of the measures referred to in points a) to f)

...

#### § 40

(1) The provider shall notify the fact to the court within 24 hours that

- a) a patient was hospitalized according to S. 38 paragraph 1 point b) and c); ...
- b) additional restraints according to S. 39 Para 1 point b) to g) have been used by a patient who initially was hospitalized on the basis of their consent.

(2) Hospitalization and additional restraints are not to be notified to the court if a subsequent consent is verifiably given within a period of 24 hours.

...

## CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

Oviedo, 4.IV.1997

### Preamble

The member States of the Council of Europe, the other States and the European Community, signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the [Convention for the Protection of Human Rights and Fundamental Freedoms](#) of 4 November 1950;

Bearing in mind the [European Social Charter](#) of 18 October 1961;

Bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing in mind the [Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data](#) of 28 January 1981;

Bearing also in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;



Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine,

Have agreed as follows:

## **Chapter I – General provisions**

### **Article 1 – Purpose and object**

Parties to this Convention shall 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.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

### **Article 2 – Primacy of the human being**

The interests and welfare of the human being shall prevail over the sole interest of society or science.

### **Article 3 – Equitable access to health care**

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

### **Article 4 – Professional standards**

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

## **Chapter II – Consent**

### **Article 5 – General rule**

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

### **Article 6 – Protection of persons not able to consent**

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.
2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.  
The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.
3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.
4. The individual concerned shall as far as possible take part in the authorisation procedure.

5. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.
6. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

#### **Article 7 – Protection of persons who have a mental disorder**

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.

#### **Article 8 – Emergency situation**

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

#### **Article 9 – Previously expressed wishes**

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

### **Chapter III – Private life and right to information**

#### **Article 10 – Private life and right to information**

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

### **Chapter IV – Human genome**

#### **Article 11 – Non-discrimination**

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

#### **Article 12 – Predictive genetic tests**

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

#### **Article 13 – Interventions on the human genome**

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

#### **Article 14 – Non-selection of sex**

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

### **Chapter V – Scientific research**

#### **Article 15 – General rule**

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

#### **Article 16 – Protection of persons undergoing research**

Research on a person may only be undertaken if all the following conditions are met:

- i. there is no alternative of comparable effectiveness to research on humans;
- ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
- iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;
- iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;
- v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

#### **Article 17 – Protection of persons not able to consent to research**

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:
  - i. the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;
  - ii. the results of the research have the potential to produce real and direct benefit to his or her health;
  - iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
  - iv. the necessary authorisation provided for under Article 6 has been given specifically and in writing; and
  - v. the person concerned does not object.
2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:
  - i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;
  - ii. the research entails only minimal risk and minimal burden for the individual concerned.

#### **Article 18 – Research on embryos *in vitro***

7. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
8. The creation of human embryos for research purposes is prohibited.

### **Chapter VI – Organ and tissue removal from living donors for transplantation purposes**

#### **Article 19 – General rule**

3. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.
4. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

#### **Article 20 – Protection of persons not able to consent to organ removal**

3. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.



4. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:
  - i. there is no compatible donor available who has the capacity to consent;
  - ii. the recipient is a brother or sister of the donor;
  - iii. the donation must have the potential to be life-saving for the recipient;
  - iv. the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;
  - v. the potential donor concerned does not object.

## **Chapter VII – Prohibition of financial gain and disposal of a part of the human body**

### **Article 21 – Prohibition of financial gain**

The human body and its parts shall not, as such, give rise to financial gain.

### **Article 22 – Disposal of a removed part of the human body**

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

## **Chapter VIII – Infringements of the provisions of the Convention**

### **Article 23 – Infringement of the rights or principles**

The 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 at short notice.

### **Article 24 – Compensation for undue damage**

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

### **Article 25 – Sanctions**

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

## **Chapter IX – Relation between this Convention and other provisions**

### **Article 26 – Restrictions on the exercise of the rights**

1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

### **Article 27 – Wider protection**

None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.

## **Chapter X – Public debate**

### **Article 28 – Public debate**

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.

## **Chapter XI – Interpretation and follow-up of the Convention**

### **Article 29 – Interpretation of the Convention**

The European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

- the Government of a Party, after having informed the other Parties;
- the Committee set up by Article 32, with membership restricted to the Representatives of the Parties to this Convention, by a decision adopted by a two-thirds majority of votes cast.

### **Article 30 – Reports on the application of the Convention**

On receipt of a 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.

## **Chapter XII – Protocols**

### **Article 31 – Protocols**

Protocols may be concluded in pursuance of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying, accepting or approving the Convention.

## **Chapter XIII – Amendments to the Convention**

### **Article 32 – Amendments to the Convention**

1. The tasks assigned to "the Committee" in the present article and in Article 29 shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.
2. Without prejudice to the specific provisions of Article 29, each member State of the Council of Europe, as well as each Party to the present Convention which is not a member of the Council of Europe, may be represented and have one vote in the Committee when the Committee carries out the tasks assigned to it by the present Convention.
3. Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.
4. In order to monitor scientific developments, the present Convention shall be examined within the Committee no later than five years from its entry into force and thereafter at such intervals as the Committee may determine.
5. Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33 and to any State invited to accede to it in accordance with the provisions of Article 34.
6. The Committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The Committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

7. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

## **Chapter XIV – Final clauses**

### **Article 33 – Signature, ratification and entry into force**

1. This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.
2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.
3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present article.
4. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

### **Article 34 – Non-member States**

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, paragraph d, of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.
2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

### **Article 35 – Territories**

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.
2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.
3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

### **Article 36 – Reservations**

1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2. Any reservation made under this article shall contain a brief statement of the relevant law.
3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.
4. Any Party which has made the reservation mentioned in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

#### **Article 37 – Denunciation**

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.
2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

#### **Article 38 – Notifications**

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

- a. any signature;
- b. the deposit of any instrument of ratification, acceptance, approval or accession;
- c. any date of entry into force of this Convention in accordance with Articles 33 or 34;
- d. any amendment or Protocol adopted in accordance with Article 32, and the date on which such an amendment or Protocol enters into force;
- e. any declaration made under the provisions of Article 35;
- f. any reservation and withdrawal of reservation made in pursuance of the provisions of Article 36;
- g. any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at Oviedo (Asturias), this 4th day of April 1997, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.