

projekt IT medik

Lékařská Fakulta v Hradci Králové



Donation and Harvest of Cells and Tissues

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OP Vzdělávání
pro konkurenceschopnost



INVESTICE DO ROZVOJE VZDĚLÁVÁNÍ

Schedule of the Presentation

- The term “Donation”, its principles and organization
- Ethical and legal aspects of donation
- The influence of traditions and religion on the practice of cell and tissue donation
- Donor eligibility assessment
- Technique of cell and tissue harvest
- Donation of cells and tissues for manufacturing of advanced medicinal products



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Schedule of the Presentation

- Presentation of donation issues to the public
- Evaluation of donation and harvest activities in the Czech Republic and in the EU
- Examples of evaluation of trends of cell and tissue donation activities
- Conclusions
- Recommended study sources

List of used abbreviations

- AATB American Association of Tissue Banks
- APASTB Asian Pacific Association for Surgical Tissue Banking
- AMP Advanced Medicinal Products
- BATB British Association of Tissue Banks
- CR Czech Republic
- DL Diagnostic Laboratory
- EATB European Association of Tissue Banks

List of used abbreviations

- EC European Commission
- EPR European Parliament and Council
- EU European Union
- UHHK University Hospital Hradec Králové
- MH Ministry of Health
- NHBD Non heart-beating donor

List of used abbreviations

- PE Procurement Establishment
- SIDC State Institute for Drug Control
- TE Tissue Establishment
- TV Television

Donation and Harvest of Cells and Tissues

- Donation – expression of the will of an individual to donate own cells, tissues or organs
- Harvest (collection, procurement, withdrawal) – medical procedure making possible to turn the wish of the donor to the reality

Principles of cell and tissue donation – criticism of approaches used in the past

- In the Czech Republic the differences between terms donation and harvest were not distinguished well in the past ,most attention was concentrated on the technical (medical or surgical) procedures connected with the cell, tissue or organ harvest
- There was a lack of clear rules for protection of the rights of donors (both living and deceased)
- This situation was repeatedly criticized in the public media, especially after 1989,mostly in connection with tissue harvests performed in deceased donors

Example of Criticism of the Tissue Harvest Practice in the Czech Republic

Record of the Czech Radio English Broadcast 21st December 2001

Source: Czech Radio 7, Radio Prague. All rights reserved. © Copyright 1996, 2012 Radio Prague. URL: <http://www.radio.cz/en/article/11228>

Current Affairs - Czechs exporting body parts?

[2001-12-21] By Nicole Klement

To hear the following story in Real Audio, click here:

The field of medical research has developed substantially since the fall of Communism, but in some areas, it seems, the law hasn't been able to keep up. Claims were recently made in the press that several Czech hospitals were exploiting a legal loophole that allows them to harvest human tissue without the patient's consent - which is legal - but then sell it abroad - for profit - which is not illegal, but not very ethical either. Radio Prague's



Operation

For the last decade the Czech Republic has been struggling to update and amend laws dealing with scientific research. A new law on transplants is still being discussed in parliament, and the papers claimed this week that several Czech hospitals and a private export firm have been using a legal loophole to create a market where human body tissue is harvested and sold abroad for profit. By law hospitals are allowed to remove tissue from dead patients without the patient's or their relatives' consent. But the current law doesn't explicitly ban or regulate the sale of human tissue.

Pavel Meriška is the head of the tissue bank at Charles University's affiliated hospital in the town of Hradec Králové. "There are two systems in the world concerning transplant legislation. First is the so called opt-in system where the donor must say yes I would like to be a donor after my death and this is expressed by a donor card. The other system is called opt-out and it is typical for Austria and Belgium and it is based on the fact that someone can say that they would not like to become a donor after death. With this system the person would have to put themselves on a computerised list of people rejecting donation. This is the system that is prepared in the new transplantation law in the Czech Republic."

But the new law has not yet passed through the Upper House.

So hospitals are left to work with the old one, which is not exact enough to cover all aspects of donor rights.

"We have a very old guidelines that says that the patient is a potential donor unless they write a letter that says otherwise. But in my 20 years of practice I have never seen such a letter. So, in my practice I accept any opposition to autopsy or harvesting that is expressed by the family."

Human tissue from the Czech Republic is quite sought after, because testing of body parts is above international standards, and post mortem are performed on 80% of bodies. The figure is far lower abroad - across the border in Austria, autopsies are performed in only one death in ten.

Many doctors say selling body parts for profit is simply unethical. The deceased patient has not usually given their consent, and - of course - there is money involved. It remains to be seen what will remain of this unusual trade once the new transplant law has been passed.

Audio version of the text from the previous slide

Click on the Icon:



Czech radio broadcasting In English 21.12.2001.mp3

Cell and tissue donation - international legal norms and recommendations

- Convention on Biomedicine and its Additional Protocol include the principle of voluntary and unpaid donation .
- The same principle is included in the Directive of the European Parliament and Council No. 2004/23/EC and 2010/45/EU and Directive of the European Commission No.2006/17/EC and in the recommendation of the Council of Europe from 2002

Principles of Cell and Tissue Donation in the EU

- Donation is voluntary and non-remunerated (unpaid donation)
- The principle of the voluntary donation described in the Convention of Biomedicine strongly protects autonomy of donors both living and deceased
- The financial gain of the donor or of the next of kin of the donor in connection with donation of cells, tissues or organs is excluded

Principles of cell and tissue donation – compensation of financial losses connected with donation

- The principle of unpaid donation does not exclude, however :
- In living donors:
- Compensation of expenses connected with the travel to the place of harvest or with hospitalization
- Compensation of lost wages
- In deceased donors in the Czech Republic:
- Governmental financial contribution covering small part of burial expenses

Principles of Cell and Tissue Donation in the EU

- Organization of donation and harvest of tissues needs special skill, in deceased donors the best management system was elaborated in Spain, we are talking about the Spanish model.
- Special TPM (Transplant Procurement Management) courses are organized by certified institutions
- In the Czech Republic transplant coordinators have existed since the 90s of the last century
- Each Czech organ transplantation centre has, now several certified coordinators ,the new position of specialized tissue coordinators is being established in some transplant centres

University in Barcelona organizes certified cell and tissue donation courses



TPM Advanced Course in Tissue Banking Management
3rd - 5th March 2009 Rome Italy

Pavel Měříčka



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Cell and tissue donation - ethical and legal issues

- Requirements of the Convention of Biomedicine – protection of the autonomy of the donor
- Living donors- two options:
 - a) Surgical or other medical procedure is performed only because of donation
 - b) The tissue removed during therapeutical surgical procedure or during the delivery can be used for transplantation- these tissues are called surgical residues, examples are femoral heads, vena saphena, skin, placenta, etc.

Cell and tissue donation – ethical and legal issues

- Cells or tissues can be harvested in living donors only with the informed consent of the donor
- In children or protected adults the harvest is possible only with the informed consent of parents or legal governors
- This concept is applied also in case of surgical residues

Cell and tissue donation – ethical and legal issues – vulnerable donors

- The bioethical convention identifies individuals requiring special protection, this category is called vulnerable donors and includes:
 - 1.Children
 - 2.Protected adults
 - 3.Soldiers in the ground service
 - 4.Prisoners
 - 5.Persons after capital punishment
- Conditions for donation in the group 1 and 2 are mentioned above, persons included in the groups 3-5 are excluded from donation

Cell and tissue donation – ethical and legal issues

- Deceased donors: 2 systems
- Presumed dissent – opting-in system (USA, UK) The donor must express during life his/her wish to donate by the way described by the law – usually by holding of a donor card

Cell and tissue donation – ethical and legal issues

- Presumed consent is a basis of transplantation acts of many states of the continental Europe. This approach was first applied in the French Transplantation Act from the 70s of the last century (Cailavet Act, 1976). All citizens are regarded as donors. The Act defines under which conditions it is possible to refuse donation.
- Since the 90s the modern methods of registration of refusals have been in operation, e.g. by registration in the National register of persons rejecting post-mortem donation.

Cell and tissue donation - current regulation in the Czech Republic

- Tissue donation is regulated by the Transplantation Act No. 285/2002 Sb., its last novel was approved in 2013 and by the Decree of the Ministry of Health No. 114/2013 Sb.
- Living donors – informed consent is always required
- Deceased donors – presumed consent is applied
- Minors and protected adults - informed consent of parents or legal governors is always required
- Prisoners are excluded from donation
- Military ground service and capital punishment do not exist in the Czech Republic, now

Cell and tissue donation –current regulation in the Czech Republic

- The dissent with post-mortem donation can be expressed by following ways: Registration in the National Register of Persons Rejecting post-mortem Donation, written declaration, or oral statement in the presence of a whiteness
- The donors family and/or proxy must be always informed about the planed post-mortem harvest-this approach is called soft variant of the presumed consent
- Attending physician, mostly anesthetist , is obliged to refer the potential donor to the pertinent organ transplantation centre and to inform the donor's family.

Cell and tissue donation – current regulation in the Czech Republic

- Transplantation Act deals with the following cell and tissues: human body building parts including surgical residues, haematopoietic cells obtained from bone marrow, peripheral blood and cord blood.
- It does not deal with the peripheral blood and its components, reproductive cells ,embryonic and fetal tissues and organs, hairs and nails
- It does not deal with the human milk

Cell and tissue donation - current regulation in the Czech Republic

- Cell and tissue donation is regulated also by the Act No. 296/2008,Sb., that implements the Directive No.2004/23/EC and by the Decree of the Ministry of Health No. 422/2008, that implements the Directive No. 2006/17/EC
- This act deals also with reproductive cells that were not included in the Transplantation Act

Cell and tissue donation - current regulation in the Czech Republic

- The Act No. 296/2008,Sb., defines the conditions under which the cell or tissue procurement can be performed – only in specialized facilities, procurement (PE) or tissue establishments (TE) that are licensed by the competent authority, ie. by the State Institute for Drug Control (SIDC)
- For each type of cell or tissue special license is granted by SIDC The collected cells and tissues can be sent only to licensed TE
- Special license is needed also for procurement of cells and tissues for manufacturing advanced medicinal products. The collected cells and tissues can be sent to the manufacturer only from licensed TE.

Cell and tissue donation - current regulation in the Czech Republic

- Penalties for breaking the law are included in :
- Novel of the Penal Act approved in 2002: New criminal action - unauthorized handling with tissues and organs was defined
- Offence Act: Advertising of availability of human cells and tissues ,financial stimulation of donation and breaking the anonymity between the donor and the host are offences
- The Act No 296/2008 Sb. defines executive offences and financial penalties for breaking the rules settled by this norm.

Cell and tissue donation –influence by traditions and religion

- Traditions and religion influence the practice of cell and tissue donation worldwide
- Living donors: Catholic Church rejects donation of reproductive cells and tissues
- The same is prohibited in the Islam religion
- Judaism actively supports donation of reproductive cells and tissues
- Catholic Church rejects donation of embryonic and fetal tissues

Cell and tissue donation –influence of traditions and religion

- Post-mortem tissue donation is accepted by Christian Churches with the exception of Mormons.
- Protestant Churches regard donation as an individual decision of a Church member with the aim to help.
- Catholic believers respect official standpoint of the Church authorities, if such standpoint exists
- A strong official support of post-mortem tissue and organ donation was expressed by the statement of the Pope John Paul II presented personally by the Pope at the Transplantation Society Congress in Rome in 2000
- Judaism – the possibility of post- mortem tissue donation is not excluded.

Cell and tissue donation – influence of traditions and religion

- Buddhism actively supports post-mortem tissue donation
- Islam – post mortem donation is generally possible, the practice is, however influenced by local religious schools. An example from Malaysia: A Fatwa Committee-committee of high Priests decides if the use of particular medical technologies is not in contradiction with the religious rules
- Shintoism (Japan) post –mortem donation and harvest are excluded

The influence of traditions and religion on the use of xenogeneic tissues

- Christian Churches do not have objections against clinical application of xenogeneic tissues
- Judaism and Islam do not approve transplantation of tissues originating from unclean animals, e.g. from pigs
- The use of such tissues is, however possible in extraordinary situations if it is approved by religious authorities – practical examples exist from Israel and from the former Soviet Union, eg. from Bashkiria in 1989

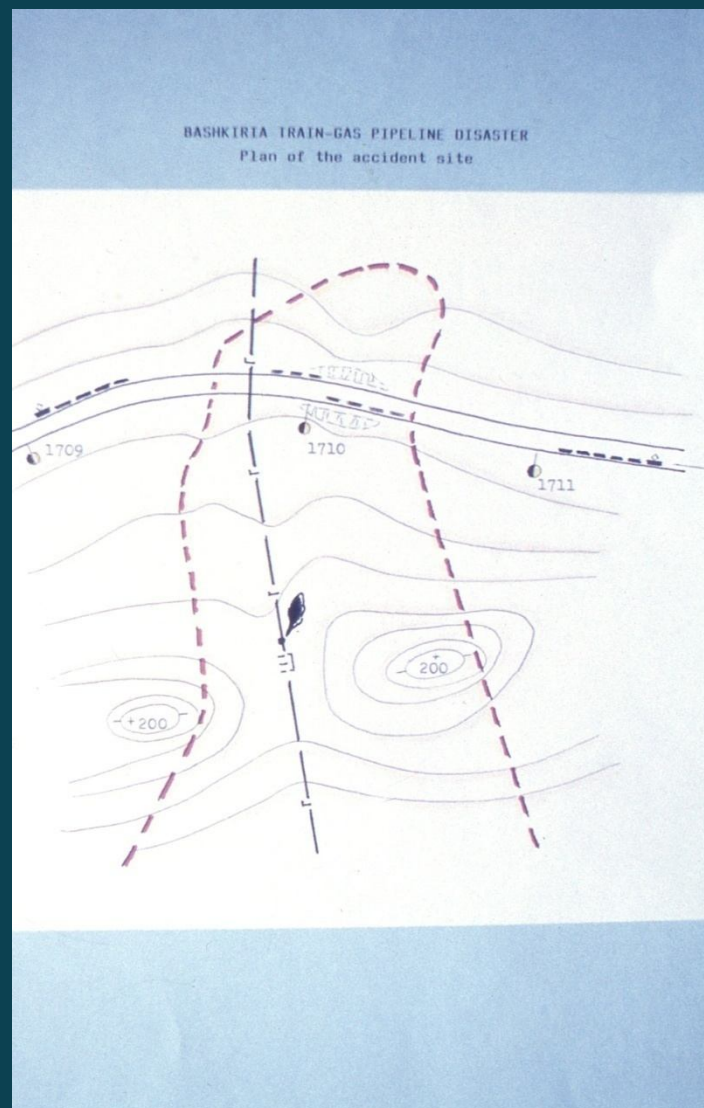
Historical picture of pigskin harvest in the premises of the Tissue Bank UHHK (1986)



Influence of traditions and religion on the use of xenogeneic tissues under extraordinary situations

- Israel: Pigskin grafts were used with consent of religious authorities in the burned soldiers in the Arab-Israel Conflict in 1973
- In June 1989, the author took part in manufacturing of pigskin grafts for treatment of victims of the train-gas pipeline disaster in Bashkiria (former Soviet Union). The disaster was caused by explosion of gas released from the damaged pipeline. It happened in the moment when two fast trains with more than 1000 passengers were passing through the valley filled with gas – see next slide.
- The managers of the tissue bank in Ufa, capital of Bashkiria, were believing moslems and said that the grafts could be used as they were life saving

Plan of the disaster site (train-gas pipeline disaster) in Bashkiria in June 1989



Harvest of viable pigskin xenografts in the Ufa Tissue Bank (Alloplant) – author in the right corner



Cell and Tissue Donor Categories

- Living donors
- Deceased donors:
 - -Brain Death Donors
 - -Non Heart Beating Donors (NHBD)

Donor Eligibility Assessment – Contraindications of Tissue Harvest

- General contraindications of tissue withdrawal for autologous and allogeneic use are defined in the Directive 2006/17/EC and in the Czech Republic in the Decree No. 422/2008 Sb. Special contraindications are well described in the Recommendation of the Council of Europe: Guide to Safety and Quality Assurance for Organs, Tissues and Cells and in standards of voluntary tissue banking associations, such as American Association of Tissue Banks (AATB), British Association of Tissue Banks (BATB), European Association of Tissue Banks (EATB) and Asia Pacific Association for Surgical Tissue Banking (APASTB)
- Examples of contraindications of tissue harvest in a deceased donor are listed in the next slides.

Donor Eligibility Assessment – Contraindications of Tissue Harvest

- Examples of contraindications of tissue harvest in a deceased donor:
- Unknown cause of death
- History of a disease of unknown etiology
- History of a malignant disease
- History of Creutzfeld-Jacob disease (CJD) including the new variant or of rapidly progressive dementia
- History of treatment with the human growth hormone or of allotransplantation of dura mater, cornea and sclera

Donor Eligibility Assessment – Contraindications of Tissue Harvest

- History of xenotransplantation
- Systemic bacterial, viral, mycotic or parasitary infection or signs of infection in the region of planed tissue harvest
- History or clinical or laboratory proof of AIDS, hepatitis B and C and infection with the human lymphotrope virus (HTLV)
- History of vaccination by viable vaccines
- History of systemic autoimmune disease
- Chronic hemodialysis
- Presence of other risk factors in the donor (see next slides)

Donor Eligibility Assessment – Donor Screening


- During the eligibility assessment process the data are collected to exclude the risk of transmission of:
- Infection
- Malignancies
- Toxic substances
- Results of collection of such data may be confirmed by clinical examination including using imaging techniques, laboratory testing or, in deceased donors by autopsy that is obligatory in the Czech Republic

Donor Eligibility Assessment – Donor Screening

- Living Donors:
- Medical history assessment aimed to exclusion of risk factors of donation, usually by standard questionnaire evaluated by a physician of the procurement or tissue establishment. The possibility of self-exclusion of the donor is included in the questionnaire
- Deceased donors:
- Medical history assessment as mentioned above (final report and/or consultation with the attending physician, family interview). Results are recorded in the standard tissue donor form issued by the Transplantation Coordination Centre (see next slides)

Czech Tissue Donor Record Form –page 1

PRŮVODNÍ LIST ODEBRANÉ TKÁNĚ PRO TKÁŇOVÉ ZAŘÍZENÍ


 Místo odběru Odběrový tým Datum identifikace dárce a posouzení zdravotní způsobilosti

IDENTIFIKACE DÁRCE

Jméno a příjmení dárce:		Rodné číslo:			
Příčina smrti:					
Datum úmrtí:		Krevní skupina a Rh faktor:		Pojišťovna:	
Hodina úmrtí:		Hmotnost:		Výška:	

Virologie a serologie

HbsAg:		Anti-HCV:		RRR:	
Anti-HbcAg:		CMV IgG		TPLA/TPHA:	
HIV 1,2, p24:		CMV IgM			

ODBĚR

Specifikace tkáně: ☐ SRDCE ☐ CÉVNÍ ŠTĚP

JINÉ

Datum a hod odběru: dne . / . . 20 . . v . . hod. . . min.

Odebírající chirurg:	MUDr.	Pracoviště:	
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Tělo zemřelého dárce bude převezeno na oddělení patologie/
soudního lékařství (adresa):

Posouzení způsobilosti dárce

	ANO	NE	Není známo
Neznámá příčina úmrtí	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anamnéza choroby neznámé etiologie	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cestovatelská anamnéza	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anamnéza chronické systémové autoimunitní nemoci	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anamnestické údaje o otravě			
kyanid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
olovo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
rtuť	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
zlato	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
radiace	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
jiné	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Posouzení vhodnosti dárce	ANO	NE	Není známo
Chronická hemodialýza v anamnéze	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neurochirurgický zákrok v anamnéze	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Současná nebo minulá anamnéza zhoubné choroby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Primární bazální buněčný karcinom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Karcinom in situ děložního čípku	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Primární nádor CNS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Creutzfeldt-Jakobova nemoc	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anamnéza rychlé progresivní demence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anamnéza degenerativní neurologické nemoci	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Přijemce hormonálních preparátů z lidské hypofýzy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Přijemce xenotransplantátu	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Přijemce transplantátů	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
oční rohovka	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
skléra	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
tvrdá plena mozková	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
jiné	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Systémová infekce nezvládnutá v době dárčovství	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Léčba imunosupresivními preparáty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indikace, že výsledky testů krevních vzorků budou neplatné pro hemodulci	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stopy po vpichu	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tetování	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
U DCD (donor after cardiac /circulatory death):			
uložení těla zemřelého při snížené teplotě + 4 °C (počet hodin)		
uložení těla zemřelého v prostředí, jehož teplota není snížena (počet hodin)		
U dětských dárců mladších 18 měsíců anamnestické údaje o matce:			
HIV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
hepatitida B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
hepatitida C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HTLV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Odpovědná osoba odběrového zařízení (případně pověřený odběrový chirurg):			
Jméno:	Podpis:		
Dárce identifikoval a posouzení vhodnosti provedl (případně pověřený odběrový chirurg):			
Jméno:	Podpis:		
Pracoviště:			

LIST A: zůstává na pracovišti provádějící odběr tkáně

KOORDINAČNÍ STŘEDISKO TRANSPLANTACÍ, Ruská 85, 100 00 Praha 10, email:sekretariat@kst.cz, tel: + 420 272 737 475, fax: + 420 271 019 356

Donor Screening - risk factors

- Living Donors:
- Hazardous sexual behavior –promiscuity, homosexuality. Paid sex in the last 6 months
- Intravenous drug abuse
- History of travel to Subsaharian Africa in the last 6 months
- History of incarceration in the last 6 months
- History of tatoo in the last 6 months

Donor Eligibility Assessment – Clinical and Laboratory Examination of the Donor

- Living Donors:
- Clinical examination
- Exclusion of oncological diseases including the use of imaging techniques or biopsy, if necessary,
- Exclusion of clinical signs of acute infection
- Laboratory examination- serology testing for HIV, hepatitis B and C and syphilis in a licensed diagnostic laboratory, bacteriological and mycological tests, if necessary
- Assessment of the morphological and laboratory quality parameters of harvested cells and tissues during harvest or after it, including evaluation the results of bacteriological and mycological swabs

Donor Eligibility Assessment - Clinical and Laboratory Examination of the Donor

- Deceased donors:
- Clinical examination of the donor including use of imaging techniques or biopsy to exclude oncology disease
- Exclusion of clinical signs of acute infection or infection of the tissue to be procured
- Laboratory testing serology for HIV, hepatitis B and C and syphilis in the licensed diagnostic laboratories, evaluation of hemodilution of taken blood samples
- Assessment of the morphological and laboratory quality parameters of harvested tissue during harvest or after it including evaluation of the results of bacteriological and mycological swabs

Donor Eligibility Assessment – Serological Testing of Donors

- Since 2008 it has been necessary to perform donor serological testing only in licensed diagnostic laboratories (DL) (Act No 296/2008Sb.)
- Similar rule was introduced in the USA in 1993 already (FDA Interim Regulation)
- The Procurement or Tissue Establishment is obliged to send collected donor blood samples to a licensed laboratory according to the conditions settled by a cooperation agreement

Technique of cell and tissue harvest

- Living donor – harvest is performed as a standard medical or surgical procedure
- Deceased donors - 3 options:
- Multiorgan and tissue harvest at operating rooms
- Aseptic tissue harvest in an operating room in a NHBD.
- Non aseptic harvest during autopsy – it is practiced by many tissue bank in the world, in the University Hospital Hradec Králové it is not performed
- Tissue harvest at the premises of funeral homes is forbidden in the Czech Republic

Examples of cell and tissue harvests

In a living donor:

- Use of surgical residues
- Harvest of haematiopoietic progenitor cells:
- Harvest of bone marrow by punctures of iliac crest bone
- Separation of peripheral blood progenitor cells
- Cord blood collection
- Collection of reproductive cells –sperm, oocytes

Examples of cell and tissue harvest-time limits

- In deceased donors we distinguish:
- Aseptic harvest before 2 hours after death – multiple organ and tissue harvest mostly in brain death donors
- Aseptic harvest after 2 hours after death till 24 hours if the dead body was cooled to +4°C or till 12 hours after death without cooling of the dead body

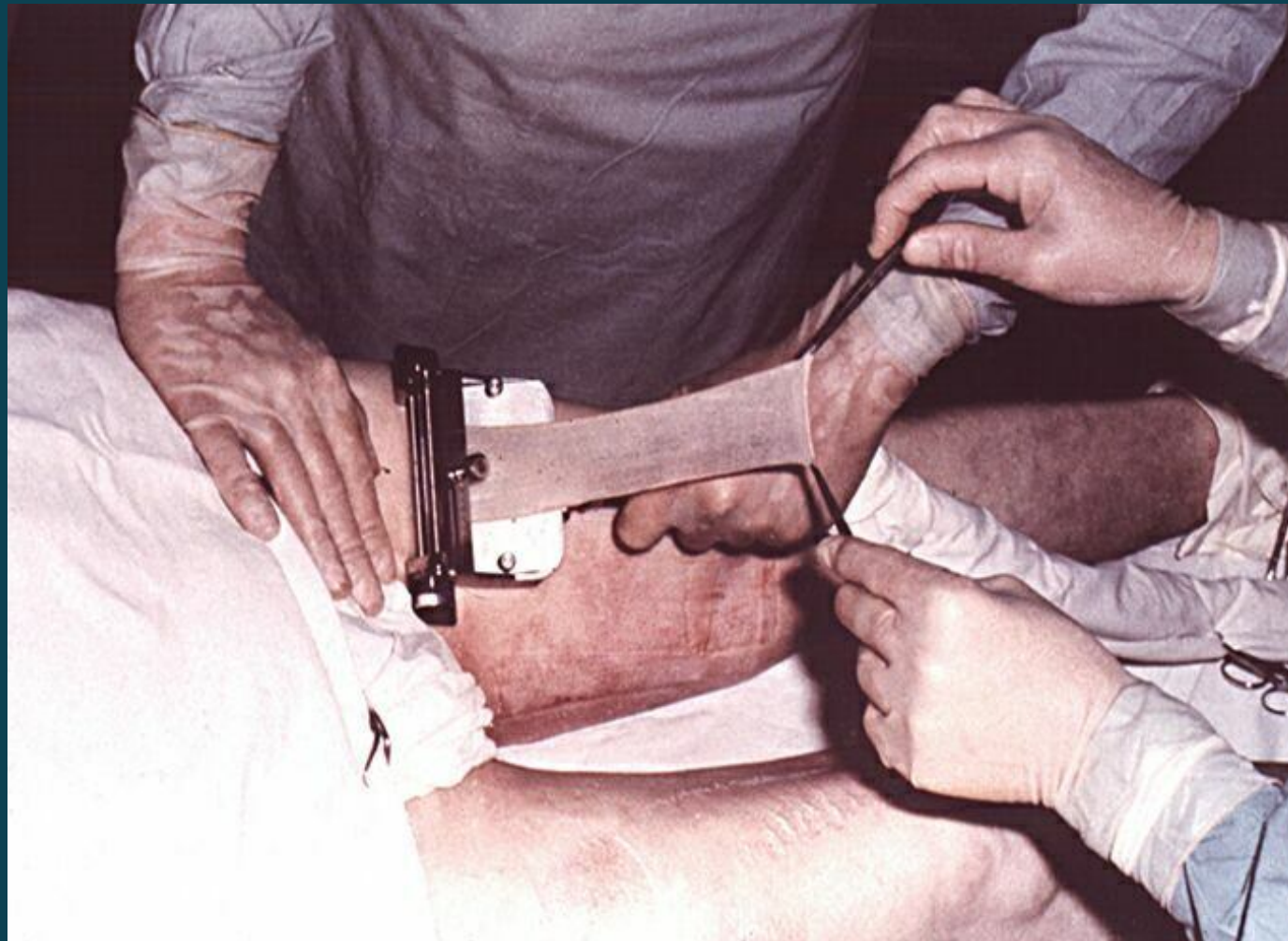
Technique of cell and tissue harvest

- Aseptic harvest is performed by sterilized surgical instruments after surgical disinfection of skin of the region of harvest and draping the donor body by standard sterile surgical drapes
- The cells or tissues are collected only into certified sterile packaging material (jars, bags) provided by the TE
- Blood samples are always taken before or after harvest for serological tests in diagnostic laboratories
- Proper reconstruction of the donor's body after harvest is performed
- The environment of the operating room is regularly monitored and checked by bacteriological swabs or aeroscopy

Historical picture (1985) showing preparation of the donor's body for tissue harvest in an operation room of the tissue bank



Historical picture (1985) showing skin harvest in a deceased donor by air dermatome



An operating nurse prepares sterile surgical instruments, draping material, bacteriological swabs and certified jars for tissue harvest in a deceased donor (2015)



A set of sterile surgical instruments for bone and fascia harvest in a deceased donor (2015)



A set of sterile surgical instruments for bone and fascia harvest in a deceased donor . Suturing material in the right upper corner (2015)



Donation and Harvest of Cells and tissues for manufacturing of advanced medicinal products (AMP)

- It is possible only with the informed consent:
- -of a living donor
- - of a deceased donor expressed during his/her life or with the consent of the next-of kin
- The most frequent are the collections of tissues for manufacturing autologous AMP, such as cultured keratinocytes, chondrocytes, mesenchymal cells, limbal cells etc. These products can be used only within approved clinical trials Registration of AMP is possible only at the level of the EU (European Medicines Agency-EMA in London, UK).
- There are, however, only few of centrally registered AMP s available now ,the most AMPs are used within clinical trials.

Donation and harvest of cells and tissues for manufacturing advanced medicinal products

- The manufacturer of AMP can obtain cells and tissues only from a licensed TE on basis of agreement between the manufacturer and TE. This type of harvest must be included in the license of the TE issued by a local competent authority (SIDC in case of Czech Republic). If manufacturing is performed outside of the Czech Republic the export of collected tissue and reimport of the AMP must be approved by the Ministry of Health.
- Donor screening, clinical and laboratory examination including serological testing in licensed DL must be performed in the same way as described above.

Presentation of donation activities to the public and recruitment for donation

- Governmental campaigns for donation (in CR organized by Transplantation Coordination Centre)-support of post-mortem, donation in co-operation with the public TV.
- Internationally recognized slogan: Do not take Your organs to the heaven – heaven knows, we need them here.
- In the CR a new slogan: Do not let Your organs to flow
- Campaigns with presence of non-governmental or private organizations, (in CR : private TV Nova-support of bone marrow donation, Astellas company ,producer of immunosuppressive drugs - support of kidney donation from living donors)

Presentation of donation activities to the public

- The best effect is achieved by presentation of individual histories of people who underwent successful transplantation, eg.:
- Complete recovery from the disease with return to physically difficult job or return to sport activities.
- Restoration of sight
- Recent example from the University Hospital Hradec Králové – a published story of a handball player ,who underwent kidney transplantation and then took part in a world games of transplanted people (published in the internet portal: Novinky.cz in November 2015),the title page is presented in the next slide

Presentation of a return to sport activities in a patient after kidney transplantation in a portal Novinky (News).cz

Novinky.cz

Transplantace ledviny mu pomohla žít opět plnohodnotným životem

Jednačtyřicetiletý bývalý házenkář Roman Dunda byl velmi živé dítě a celé své dětství trávil neustálým sportováním. Závodně hrál od osmi let házenou a k tomu ještě dva roky badminton, později se věnoval i atletice. Kvůli své sportovní aktivitě byl pravidelně pod dohledem lékaře, který mu ve 23 letech odhalil sníženou funkci ledvin.



Poslední sniž na Černé hoře (4/2015)
FOTO: archiv Romana Dundy

pondělí 23. listopadu 2015, 8:42

Tenkrát dostal angažmá v extraligovém klubu házené HBC Jičín. Vyšetřit se nechal z vlastní iniciativy, aby se mohl každý rok pravidelně zdravotně sledovat. V momentě, kdy mu lékař sdělil diagnózu, si vůbec neuvědomoval rozsah svého onemocnění. Byl naprosto přesvědčen, že se s nemocí těla velmi rychle vypořádá a on bude hrát dál házenou. Tak to podal i svým nejbližším, tudíž nikdo z nich netušil, že se jedná o něco závažného a nevyléčitelného.

Lékaři mu nasadili imunosupresivní léky, které měly zastavit postup nemoci. Denně k tomu jezdil do Jičína na tréninky, ale jeho výkonnost byla každým dnem horší. Následovalo nevyhnutelné. Lékař mu sdělil, že musí s házenou skončit, jelikož léčba se v žádném případě neslučuje s výkonnostním sportem.

Evaluation of donation and harvest activities

- In the EU it is performed at the level of member states and at the level of the EU. The Czech TE s refer the annual data to the Transplantation Coordination Centre, where the data are processed and sent to the Eurocet database.
- These data are publically available at the website: <http://www.eurocet.org>
- At suitable occasions, such as World Kidney Day the data supporting donation are published
- Each TE is obliged publish its annual report on the internet

Evaluation of Donation and Harvest Activities

- The data on the number of deceased organ donors are evaluated and published separately:
- The total number of donors in the country per year
- The number of donors per 1 million of inhabitants per year
- In the 90 s CR belonged to the countries with the highest annual donation rate per million of inhabitants
- When the new transplant legislation came into force there was a considerable drop in the annual organ donation rate (see next slide)
- Now, there are again some signs of improvement

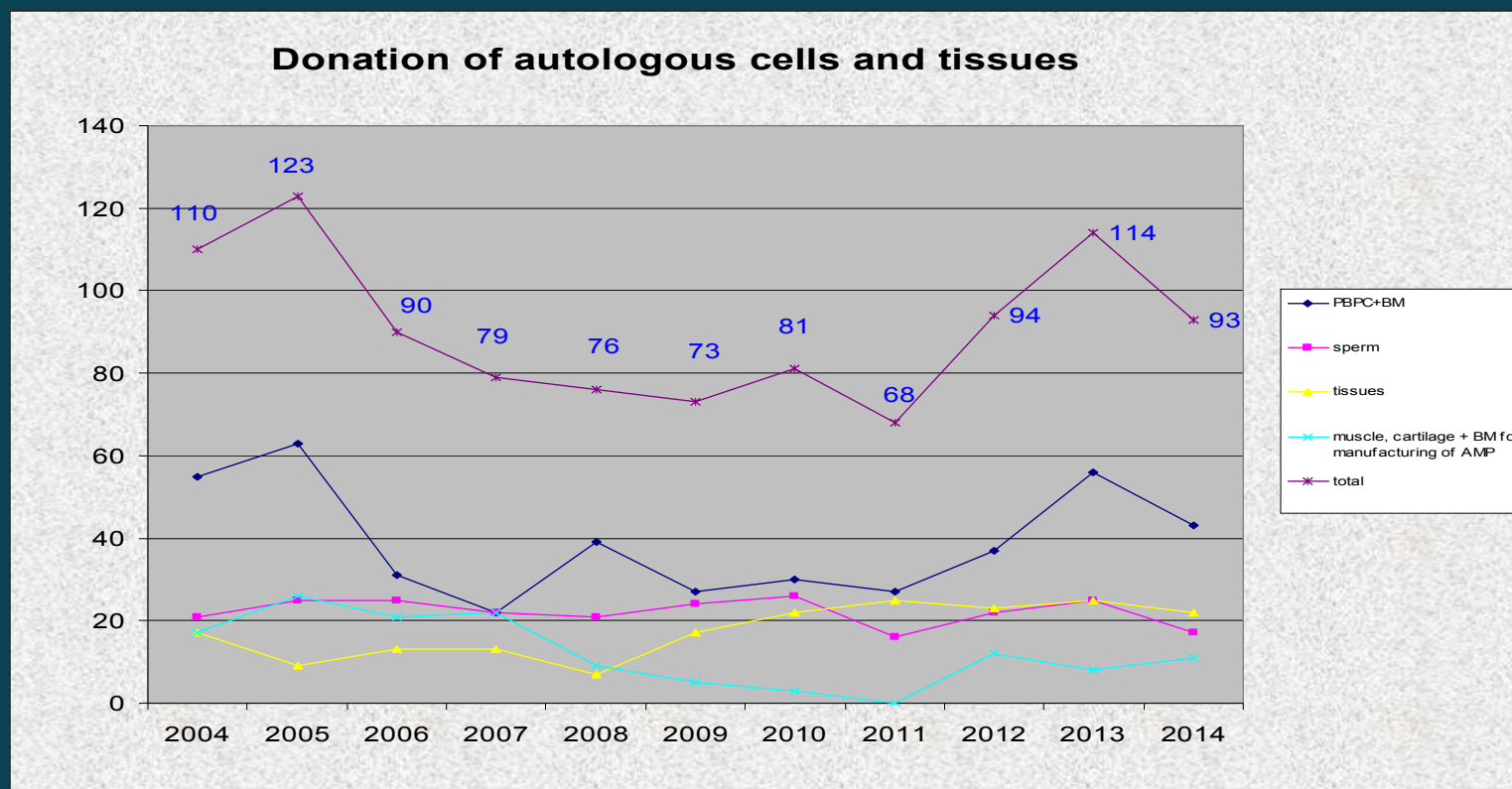
Organ donation activity in selected countries – number of deceased donors/ milion of inhabitants in 2010

Poland	1.0
Hungary	13.9
Germany	14.9
Czech Republic	19.2
USA	21.9
Estonia	24.6
Austria	25.0
Spain	34.4

Example of evaluation of trends of donation of cells and tissues for autologous use in the UHHK

- Number of donors/receivers of haematopoietic tissue – dark-blue line . It fluctuates in dependence on many factors
- Number of sperm donors for use between partners- violet line. It is relatively low and stable. Only men before radical oncology treatment are included
- Number of autologous tissue donors –yellow line. It is stable as well, only patients undergoing craniectomies are included . Skull bones are removed for replantation in future.
- Number of tissue donors for manufacturing of autologous AMP –blue line. It dropped to zero in 2011 because of legislation changes. Since 2013 all AMP s have been used only within approved clinical trials.

Examples of evaluation of trends of donation of cells and tissues for autologous use in the UHHK

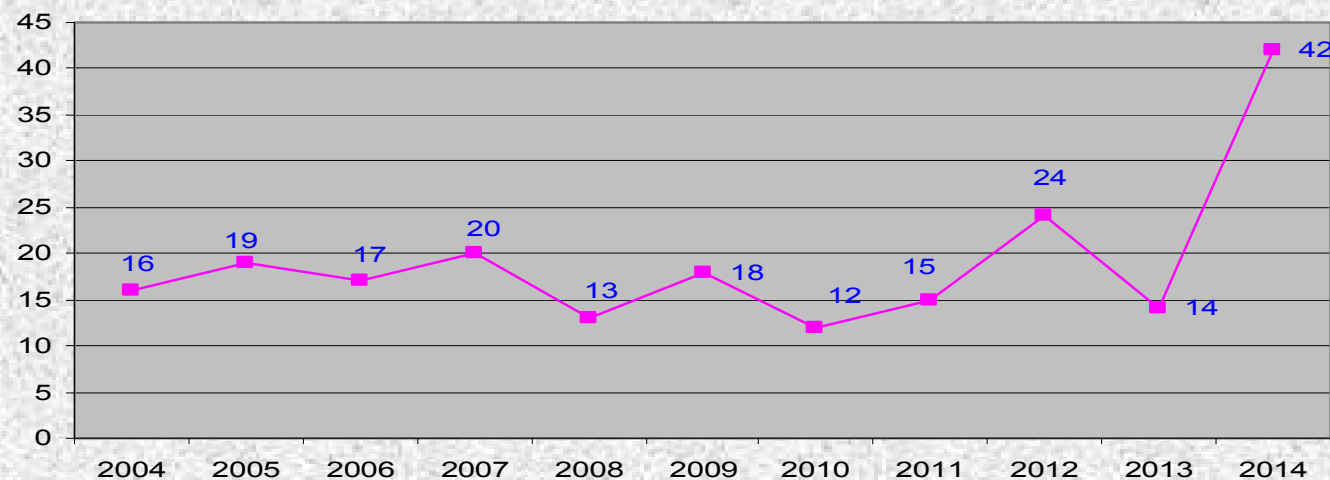


Examples of evaluation of trends of donation in the UHHK – number of deceased tissue donors

- Tissue harvests in deceased donors are performed in cooperation with the Regional Transplantation Centre. The region of the centre has approximately 1 million of inhabitants.
- Until 2013 the number of donors per year corresponded well with the average post-mortem organ donation rate in the CR
- The increase in number of donors in 2014 is caused by the start of cooperation with procurement centers specialized on harvest of vascular tissues in the Prague and Brno hospitals ,ie outside of the local transplantation centre region

Examples of evaluation of trends of tissue harvest in deceased donors in the UHHK

Donation of tissues - deceased donors



Conclusions

- The new EU rules and harmonized national legislation strengthened the protection of the rights of living and deceased donors in the CR
- There was also a considerable improvement in the governmental supervision of the quality and safety of the practice of tissue and procurement establishments

Conclusions

- The practice of harvest in deceased donors has become more difficult which led to the drop of annual donation rate in comparison with the 90s of the last century
- The experience from countries with high donation rate showed that it is necessary:
 1. To perform continuously campaigns for donation
 2. To have well organized system of donor management at the level of a hospital

Conclusions

- ◐ We must not forget that we are grateful to donors and to their families for all our achievements in the field of the cell, tissue and organ transplantation.

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