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TITLE

Regulation of Transplantation of Human Organs and/or Tissues

STUDENT'S NAME

Elen Hovhannisyan

SUPERVISOR'S NAME

Prof. Arman Zrvandyan

Abstract

The aim of this thesis is to investigate and identify the present status of the legal concept of consent worldwide and, particularly, in the Republic of Armenia. Currently, there are a few surgeries of transplantation of human organs or tissues in the RA. This field is not developed yet both in medicine and in the legal systems. There are many uncertainties in the legal regulation of transplantation of human organs and tissues.

The first part of this work examines the legal characteristics of consent and states its types. There are several types of consent across the world and each country adopted one of them according to the legal system in that country. The thesis also described different mechanisms of consent and compared their features. Speaking about the role of the consent in transplantation, there is a need to understand what the object of the surgery is. The object has its "owner', which is analyzed in the third part of this work.

The last chapter gives the picture of the mentioned problem in the RA and offers the possible solutions before and after changes in the legal regulation of the transplantation in the RA. Especially, after amendments in 2009 the whole system was changed. Because of that current regulation has contradictions with Constitution and, in general, with the legal system of RA. The main notion of consent in transplantation has changed.

To conclude, this work considered various models of consent and drawing parallels between Armenian legal framework and international practice. As a result of the research we think that there is a need of significant changes in the law and Armenian approach of the transplantation regulation.

Keywords: transplantation, human organs, human tissue, donor, deceased donor, consent, private life, dignity, ownership of organ.

Table of Contents

INTRODUCTION **4**

CHAPTER 1 Legal concept of consent. **9**

CHAPTER 2 Different Systems of consent **13**

CHAPTER 3 The ownership status of human organs and/or tissues **17**

CHAPTER 4 Armenian approach on transplantation **19**

CONCLUSION **24**

BIBLIOGRAPHY **26**

A person is not a property, so he cannot be a thing such as he might own;

For it is impossible, of course, to be at once a thing and a person,

a proprietor and a property at the same time.

The Metaphysic of Morals

Immanuel Kant

Introduction

Beginning from the 20 century the medical science developed drastically. It is possible to extend person's life in a way of changing his/her organs. This process is called transplantation. Organ transplantation is the therapeutic use of human organs involving the substitution of a non-functional organ for another one coming from a donor[1]. Clinical organ transplantation began in the mid 1950s. Patients were twins and the transplantation object was a kidney. Transplantation saves many lives and let people to live longer with donated organs.

In many cases the only available treatment for the patient is transplantation. Many Doctors consider the transplantation as lifesaving tool. In terms of quality and safety the benefit-to-risk ratio is a fundamental approach for organ transplantation. Due to the organ shortage and the life threatening indications of organ transplants, the benefits of an organ transplantation are high and more risks can be accepted than with blood or most tissues and cells treatments[2].

There are mainly 4 types of organ transplantation:

1. Autotransplantation- when both the donor and the recipient is the same person
2. Izotransplantation- when the donor is in a relative relationship with the recipient
3. Allotransplantation- organs transplanting from human to human
4. Xenotransplantation- the donor is an animal while recipient is a human

Armenian law on Transplantation of human organs and/or tissue[3] covers only allotransplantation and izotransplantation. As for the last, in case of imprisonment, the only way

[1] Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation COM(2008) 819 p. 333

[2] Organ donation and transplantation policy options at EU Level, Consultation Document 27/07/2006, p 13

[3] Law on Transplantation of human organs and/or tissue, ՀՀՊՏ 2002.05.29/16(191) ,in force since 25.11.2002 (hereinafter Law on THOT)

that person could be a donor is when he/she donates his/her organs to close relatives.[4]. The developing branch of transplantation - xenotransplantation is out of the scope of this paper, because the law covers cases when the donor is a natural person as it is described in the article 1 of the LTHOT. Autotransplantation will not be considered as well, because the consent of both donor and recipient is obvious in that case.

According to the donor, there can be two types of transplantation:

1. Ex vivo- alive donor
2. Ex mortuo- deceased donor

LTHOT covers both alive and deceased donor transplantation. Article 7 of the law states the procedure for taking organs and/or tissues from deceased donor and article 10 states the procedure for taking organs and/or tissues from alive donor. The main difference is that alive person can donate the organ which is normally has pair in the organism or part of the organ which is single in the human organism as described in the article 3.

In addressing the issue of consent for organ donation, this paper deals with the consent of deceased adults who were competent to make decisions regarding their organs when they were alive. It is fully acknowledged that in the case of minors, the right to consent remains with the parents or guardians of the deceased child.

Government decision[5] states the list of organs for donation as follows:

1. Heart
2. Kidney
3. Spleen
4. Liver
5. Lung
6. Pancreas with 12 duodenal
7. Endocrine glands
8. Heart-lung complex
9. Liver-bowel
10. Cornea
11. Skin
12. Bone

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[4] Government decision on taking the organs and/or tissues for transplantation from prisoners and stating medical care and conditions after taking organs and/or tissues, ՀՀՊՏ 2012.11.28/58(932) Հոդ.1252, in force since 29.11.2012

[5] Government decision on stating the list of organs for donation, ՀՀՊՏ 2007.05.23/26(550) Հոդ.628, in force since 24.05.2007

13. Endocrine tissue

14. Blood vessels

The list is limited, so no other organ or tissue transplantation could be covered by the LTHOT. This means that the transplantation of blood, cells or reproduction glands will not be discussed in this paper.

As all human beings have one heart, and it is prohibited to save recipient's life sacrificing donor's life. The only way to do transplantation is to take the organ (the heart) from deceased donor. It is very important to protect both recipient's and donor's rights during the process of donation. In transplantation act, the basic principle should be the privilege of donor's rights. The donor's life prioritized because he/she puts his/her life under the danger (being healthy) to safe other's life. In the case where the donor is deceased, the only aim of transplantation is saving the recipients life.

There are some advantages when the donor is deceased, for example, the organ, which is single in the organism, can be taken or there is no risk to injure the donor. Besides benefits for the recipient, transplantation must not violate deceased person's right to express the opinion on what his/her body will face after the death. Person has the right to decide whether he/she wants to become the donor after the death or not. For this purpose there are mechanisms to express the position regarding donation of the organs.

The main issue of the paper is who has the right to decide whether donate the organ/tissue or not. The donation of organs is very risky both for donor and for recipient. It is vital for donor to understand his/her actions and donate organs with his/her fully given consent. During the lifetime a person is free to decide what to do with his/her body, so no one has the right to interfere with donor's actions. But the situation differs after the death. Who is eligible to decide on other's behalf what to do with the body? The main discussion will be on the case of deceased donor's consent, the idea of consent and the ownership of the body.

No one has the right to intervene other's private life. The right to privacy is difficult to define but has come to include a wide range of overlapping and interrelated rights protecting the individual's freedom as long as his/her actions do not interfere with the rights and freedoms of others. The right to privacy is the right to individual autonomy that is violated when states interfere with, penalize or prohibit actions which essentially only concern the individual. The right to privacy encompasses the right to protection of a person's intimacy, identity, name, gender, honor, dignity, appearance, feelings and sexual orientation and extends to the home, the

family and correspondence. The right to privacy may be limited in the interests of others and under specific conditions, provided that the interference is not arbitrary or unlawful.

The European Court of Human Rights stated that the right to respect for "private life" is the right to privacy, the right to live as far as one wishes, protected from publicity. However, the right to respect for private life does not end there[6]. There are many contradicting cases regarding the medical interference to one's life. In some cases the ECHR stated that assisting person with medicines is not violation of article 8, but in some cases it is.

A person's body is an intimate aspect of his/her private life[7]and a sound mental state is an important factor for the possibility to enjoy the right to private life[8]. Factors that affect the physical integrity or mental health have to reach a certain degree of severity to qualify as an interference with the right to private life under Article 8[9]. However, the Court has also held that even minor interferences with a person's physical integrity may fall within the scope of article 8 if they are against the person's will[10].

For example, in the case Y.F. v Turkey the applicant's wife had been arrested on suspicion of assisting a terrorist organization. After several days in police custody she had been examined by a doctor and then been taken to a gynecologist against her will. The Government's argument was that the examination had been necessary for check whether she had been sexually assaulted or acted according to her will. The Court stated that there had not been both legal basis and medical necessity, so as a result, the court fond found a violation of right to private life.

In Glass v UK[11], the applicant was a child who had mental and physical disabilities. He was treated in hospital against a severe lung disease. Doctors wanted to use morphine for treating the child, but mother was against the administration of morphine for fear that it might cause the death of the child. However, doctors decided to administer morphine as they found it necessary. The Court of human rights stated that there was a violation of human rights and hospital staff had no right to act without the consent of the applicant or his relatives.

Medical treatment against a person's will is an interference with the right to private life. However, such interference may be justified in the interest of the affected person, for example for purposes of health protection[12]. In Acmanne v Belgium case[13], the European Court of Human

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[6] X v Iceland (Application no. 6825/74) 18/05/1976
[7] Y.F. v Turkey (Application no. 24209/94) 22/10/2013
[8] Bensaid v UK (Application no. 44599/98) 06/02/2011
[9] See at the same place
[10] Storck v Germany (Application no. 61603/00) 16/06/2005
[11] Glass v UK (Application no. 61827/00) 09/03/2004
[12] http://echr-online.info/physical-integrity/
[13] Acmanne v Belgium (Application no 10435/83) 10/12/1984

Rights held that a Belgian law requiring children to undergo an x-ray examination to prevent tuberculosis was not in breach of article 8 of ECHR.[14]

So, the question is “who is eligible to give consent to donate an organ and/or tissue after the death: the relatives or the person himself/herself during the lifetime?” The regulation of arise issue will allay the growth of black market of organs/tissues and raise legal awareness of population.

[14] See at the same place

Chapter 1 Legal concept of consent

Professionals debate on the question of transplantation and which system is the best for protection of human rights without clarifying what is the consent and who has the right to give it and whom. As Brazier notes “Consent is such a simple word” and is the more beguiling and elusive for that[15].

Human bodily resources have a great demand and not enough supply[16]. The demand is not only for transplantation but also for medical and scientific researches. With the development of science, it is possible to weave artificial organs, but for now, it needs more research and respectively more real organs needed for experiments[17]. This enhances the value of our bodies (its parts) and the need for donor. By virtue of their nexus to “self”, the retention and use of human material raises profound issues pertaining to the relationship between bodies and personal identity, and generates fundamental questions about who we are and what sort of society we wish to live in[18].

As long as a requirement for consent is becoming vital, different idea of “consent” prevail in official policies, and widely varying laws, practices and perceptions exist around the world. In particular, presumed consent is a concept which, despite being a widespread legal phenomenon, continues to draw trenchant criticism from various quarters[19]. The central function of consent is traditionally seen to uphold the moral principle of estimating an individual’s autonomy, that is, one’s freedom of rational self-governance and self-determination[20].

In the literature there is no single definition of the consent. Understanding of consent can differ according to the legal system of the country. In the US the definition of consent may vary on state to state basis according to the complex legal system in the country. There are some factors that determine the consent such as:

1. Age: This criteria provides the information whether a person has the basic knowledge of what is going on and what he or she is engaged in.

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[15] M. Brazier, ‘Organ retention and return: Problems of consent’ (2003) 29 Journal of Medical Ethics p.30
[16] R. Tessie, ‘Native American genetic resources and the concept of cultural harm’ (2007) 35(3) Journal of Law, Medicine and Ethics p.396
[17] Goodwin, Michele, Black Markets: The Supply and Demand of Body Parts Cambridge University Press. P14
[18] R. Tessie, ‘Native American genetic resources and the concept of cultural harm’ (2007) 35(3) Journal of Law, Medicine and Ethics p.396
[19] Price, David. Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework (Cambridge Law, Medicine and Ethics) Cambridge University Press. P4
[20] Ruth R. Fadden and Tom L. Beauchamp, A History and Theory of Informed Consent (Oxford: OUP, 1986).p23

2. Development disability: Has the person ever faced a developmental disability or any other mental incapacity, such as a brain injury or others

3. Relationship: Is the person dependant or he/she can act in accordance with his/her will.

In practice the above mentioned factors are considered in determining the absence or presence of consent in the cases of sexual activity[21]. The question of consent in sexual activity is important to define because in case of its absent there is a criminal offence against person's dignity and physical integrity. There are no certain criteria of consent in other fields such as donation in transplantation. We found that the issue here is the presence or absence of the consent in the scenario where the body is involved. The importance here is that the person gives his/her consent to involve his/her body in any activity (no matter whether it is sexual activity or donation) So, this test can be used in transplantation cases to define whether there was a consent for interfering to the person's body and donation or not. Besides these three criteria there are some more factors such as intoxication, physical disability and others.

The standard ethical procedure is one where consent is sought explicitly from the person whose rights and interests are concerned, unless the person is deemed temporarily or permanently incompetent, in which case consent is sought from a proxy or surrogate who might be best placed to know the individual's wishes. In some contexts, however, "presumed consent" may be the operating paradigm, such as in an emergency situation where it is impossible to secure consent from the patient or a proxy in time without jeopardizing the patient's life.

It is typically maintained that consent may either be explicit, implicit, or tacit. Explicit consent is an expressed consent. However, in the medical practice the implicit consent is seen more. For example, when one rolls up others sleeve to enable a blood sample to be taken[22]. Arguably implicit consent is the basis for the absence of a requirement for consent in relation to surplus tissue from the living for clinical audit, quality assurance and performance assessment[23]. In some cases consent may be tacit. Childress has described tacit consent as a "consent that is expressed silently or passively by omissions or by failures to indicate or signify dissent"[24].

Finally, legal consent may be imputed, although to some this rests on a fiction and cannot be considered a true "consent". Beauchamp and Childress are skeptical regarding the latter, stating:

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[21] Legal role of consent, https://www.rainn.org/articles/legal-role-consent
[22] J. Childress, Practical Reasoning in Bioethics (Bloomington, IN: Indiana University Press, 1977), p. 272
[23] J. Childress, Practical Reasoning in Bioethics (Bloomington, IN: Indiana University Press, 1977), p. 276
[24] J. Childress, Practical Reasoning in Bioethics (Bloomington, IN: Indiana University Press, 1977), p. 277.

"Consent should refer to an individual's actual choices, not to presumptions about the choices the individual would or should make"[25]

The Department of Health Reference Guide to Consent states "The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid"[26]. In the House of Lords in Sideway v. Governors of the Royal Bethel Hospital, Lord Daglock stated "Consent to battery is a state of mind personal to the victim of the battery"[27]. Grubb has similarly observed that "A valid legal consent is given even where the patient does not demonstrate his agreement providing that the state of mind was, in fact, that he agreed. In other words, an unexpressed actual consent in law is a valid consent."[28] This would tend toward the view that consent is a mental state of acquiescence rather than an expression of such a state, despite the more pervasive "lay" view that consent is something that a person "does".

Whether consent should be seen as either subjective or objective is a matter of policy rather than philosophical enquiry.[29] It depends upon the policy objectives which the law seeks to achieve in the particular context. There are different approaches of the consent around the globe in other contexts, with some jurisdictions defining consent as a subjective mental state ("attitudinal") and others as an objective expression of an acquiescing state of mind ("expressive"). From a moral perspective, Hurd and Alexander assert that consent is a mental state and an "exercise of the will"[30]. There should be some definite mental acquiescence in altering the rights and status of the other party.

It may seem as though consent is being regarded as a matter of form rather than substance. But the need for expression can be seen as providing reliable evidence that a "decision" was in fact made and that agreement really exists, i.e. cogent evidence of the agent's will[31]. As Simons observes, "The very act of communicating, which requires some self-consciousness and some effort to articulate feelings, at least renders it more likely that the

[25] T. Beauchamp and J. Childress, Principles of Biomedical Ethics, 6th edition. (Oxford University Press, 2008), p. 107.
[26] Human Tissue Authority Code of Practice, Consent, HTA, July 2006, par. 68.
[27] Sideway v. Governors of the Royal Bethel Hospital [1985] 1 All ER p643.
[28] Grubb, 'Consent to treatment: The competent patient', in I. Kennedy and A. Grubb (eds.), Principles of Medical Law (Oxford University Press, 1998) p109
[29] Weston, The Logic of Consent, p 140
[30] L. Alexander, 'The moral magic of consent II'(1996) 1 Legal Theory p 165.
[31] Beyleveld and Brownsword, Consent in the Law 1997, p. 187.

underlying state of mind communicated is more stable"[32]. If no expression was required, only ambiguous evidence exists that any decision was ever reached, even in terms of a subjective state of mind. Wertheimer similarly states that "In opting for a performative account of consent, I readily grant that tokens of consent are morally significant precisely because they are reliable indications of desires, intentions, choices, and the like"[33].

An explicit consent system is one where only such consent will suffice to permit removal and use of organs and tissues for donation or scientific purposes after death. This might nevertheless be the consent of the deceased, the consent of relatives (or a prioritized relative), or of a nominated representative (proxy). Interestingly, in explicit consent systems the absence of an expressed wish to donate during life is not taken as presumed evidence of a wish not to donate. To that extent, straightforward analogies with living persons break down[34].

Thus, whilst Gill states that under an explicit consent regime "if there is no evidence that an individual either wanted or did not want to donate her organs after her death, she is currently treated as though she did not want to donate"[35], this is not strictly correct. Silence does not carry such an inference or otherwise there would be evidence of an objection, which would preclude a relative from giving consent instead in almost all jurisdictions. Silence seemingly amounts to no more than a mere failure to consent[36]. However, the typical explicit consent system has been best described as a "no-objection-to-delegation" system[37]. This would appear to be the appropriate presumption as this is the default position in the absence of any decision being made by the deceased. One can therefore assert that the official stance in such instances is that there is an operative presumption that relatives are entitled to make a decision to donate unless the deceased had pre-emptively taken the matter out of their jurisdiction by making an explicit decision regarding donation before death. Although Garwood-Gowers states that "There is no such thing as "presumed consent" in philosophical or legal terms; consent is either implicit or explicit or it doesn't exist at all"[38]. The notion of tacit consent does have moral and legal validity in some contexts.

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[32] K. Simons, 'The conceptual structure of consent in criminal law' (2006) 9 Buffalo Criminal Law Review p577.
[33] Wertheimer, Consent to Sexual Relations, p. 147.
[34] T. Beauchamp and J. Childress, Principles of Biomedical Ethics, 6th edition. (Oxford University Press, 2008)
[35] M. Gill, 'Presumed consent, autonomy, and organ donation' (2004) 29(1) Journal of Medicine and Philosophy
[36] M. Mehlman, 'Presumed consent to organ donation: A reevaluation' (1991) 1 Health Matrix
[37] Decision Systems for Organ Donation from an Ethical Viewpoint, Monitoring Report Ethics and Health, Centre for Ethics and Health, The Hague, 2008 p6
[38] Garwood-Gowers, 'Extraction and use of body materials for transplantation and research purposes: The impact of the Human Rights Act 1998 p121

Chapter 2 Different Systems of consent

Countries may operate under a system of opt in, with the use of a donor card, for example, or under a system of opt out, where individuals are considered to have given consent to posthumous procurement of organs and tissue for research or medical purposes unless otherwise stated. Countries tend to operate under a sub-classification of these two systems; these are categorized as “hard” and “soft” opt in/opt out systems, with “soft” systems allowing for the opinions of relatives to be considered and “hard” systems disregarding consideration of such opinions[39].

There is quite a bit of diversity in the opt in/opt out donation systems[40]. At the one end, a hard opt out system (e.g. as exists in Austria) allows health professionals to remove tissue or organs from every adult who dies unless a person has registered to opt out; objections from relatives are disregarded. In case of children, right to object to organ removal may be exerted by the legal guardian during the lifetime. The foreigners are treated in the same way as the Austrian citizens regardless of the legal provisions in force in their home country[41]. In the other type of hard opt out system he doctor can take organs from every adult exempt the specific group, for example in Singapore Muslims chose to opt out as a group[42].

The other ultimate end is a hard opt in system, which allows health professionals to remove tissue or organs only from adults who have expressly consented to such removal, regardless of the relatives’ objections. An example could be the United States of America, where the explicit consent is needed for donation.

Soft systems operate in between. They allow for the considerations of relatives to be taken into account – but here there are critical distinctions. In some soft opt out countries, such as Belgium, health professionals can remove tissue or organs from every adult who dies, unless a person has registered to opt out, or the relatives object to removal and the relatives take it upon themselves to communicate with the health professionals. In these countries, there is no positive obligation of health professionals to consult with relatives.

In soft opt in systems, such as in England or Scotland, health professionals can remove tissues or organs from adults who had expressly consented to (or ‘authorized’) such removal, but

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[39] Douglas and Cronin, ‘The Human Transplantation (Wales) Act 2013’, p. 323
[40] Douglas and Cronin, ‘The Human Transplantation (Wales) Act 2013’, p. 325
[41] Ogan transplantation in Austria, W.Blaicker, H. Pokorny, H. Puhalla , p 41
[42] Irish Hospitak Consultants Association, Consent for Organ Donation, 28/03/2009, p4

generally health professionals will inform relatives that the deceased had opted in and the health professionals may choose not to proceed with removal if certain relatives object.

Finally, in other soft opt out countries, such as Latvia, however, health professionals can remove tissue or organs from every adult who dies, unless a person has registered to opt out, but it is standard for health professionals to actively consult with relatives to obtain their agreement at the time of the person's death. In European Court of Human Rights there are cases against Latvia in transplantation issue.

In Petrova v Latvia[43] case Ms Petrova's, an applicant's, son was involved in the car accident. Doctors classified the injuries as serious and life-threatening. They established that the death was caused by those injuries. Ms Petrova asserted that neither her son's nor her own consent was examined and the authorities acted without any legal ground. The applicant complained in substance under article 8 of the Convention. Ms Petrova argued that there was no mechanism permitting her to exercise her right to express her wishes as concerned organ removal On the other hand, the Government opposed that there are certain mechanisms such as in the absence of the relatives in the hospital, the staff has a right to carry the surgery without informing relatives which is called "Presumed Consent". However, the Court found that the way in which this "presumed consent system" had operated in practice was unclear and had resulted in circumstances whereby Ms Petrova had certain rights as the closest relative but was not informed. The Court founded that the time in which the transplantation is being processed is sufficient to inform relatives and get their consent.

In this particular case, Ms Petrova had no chance to express her consent. The Court accordingly found that the Latvian law as applied at the time of the death of Ms Petrova's son had not been formulated with sufficient precision or afforded adequate legal protection against arbitrariness. The organ transplantation of Ms Petrova's son without her being informed had not therefore been in accordance with the law, in breach of Article 8 of the Convention.

Another case involving Latvia was Elberte v Latvia[44], where the court found that taking organs and/or tissues from person without consent of relatives violate relative's rights such as right to respect for private and family life (article 8 ECHR) and prohibition of torture (article 3 ECHR). In this case Ms Elberte's husband was involved in the car accident. The autopsy was done in Riga. Doctors classified the injuries as serious and life-threatening. They established that the death was caused as a result of those injuries. At the day of the funeral, the applicant founded

[43] Petrova v. Latvia (Application no. 4605/05) 24/06/2014
[44] Elberte v. Latvia (Application no. 61243/08) 0112/2016

that legs of deceased were tied together. At that time Ms Elberte was pregnant with their second child. After two years she was informed that the tissue was taken from Petrov. The Forensic Center explained that removal was allowed, because they saw that person had not opted out. Ms Petrova confronted that passport was in their apartment in Sigulda. So, neither her husband's nor her own consent was examined and the authorities acted without any legal ground. The Court found that the applicant had suffered a lot and it could be qualified as an inhuman treatment as well as an interference to the private life.

There could be mandate choice or required consent systems in some countries. The mandate consent is separated to soft and hard types as well. In soft mandate system people can choose whether to register his personal information and consent in register. In hard mandate system people are obliged to register their consent. A system of required request would require that a person's wishes must be determined before death. Potential donors are identified in hospital accident and emergency departments and intensive care units and the individual or his/her family must be approached and their wishes in relation to organ donation determined[45].

[45] http://health.gov.ie/wp-content/uploads/2014/04/consentoptions.pdf

Chapter 3 The ownership status of human organs and/or tissues

The other side of the presented problem is the "ownership" status of human organ or tissue after the death and for which purposes they could be taken. As Childress has observed:

"If this is not my kidney, what right do I have to give it away?"[46]

One concern is that if property rights are recognized in the tissue source, that third parties such as relatives might be availed of proprietary rights in the corpses of others after their deaths. Brazier has, for instance, stated "If my relative's body is mine, be she child, mother, or sister, I may do with my property as I wish. I may elect to sell her component parts in public auction. I may donate her for display as a object of exhibition."[47] In general only the donor/source is the owner of original human material.[48]

The evolution of civilization from slavery to freedom, from regarding people as chattels to recognition of the individual dignity of each person, necessitates prudence in attributing the qualities of property to human tissue. Having property rights on others body part is something like slavery. Present conditions and development of civilization could not accept slavery.

In In Re Organ Retention Group Litigation, whilst the High Court denied there were generally any property rights in cadaveric tissue, it then refused the right of families to possess the separated tissue of their deceased offspring on the basis of the property rights of the pathologists who had conducted the post-mortems[49].Yearworth v. North Bristol NHS Trust, where it was stated that "In this jurisdiction developments in medical science now require a re-analysis of the common law's treatment of and approach to the issue of ownership of parts or products of a living human body"[50].Property refers to rights held by individuals which govern legal relations between persons with respect to the items concerned, rather than to such items themselves[51]. We need to distinguish whether human biological materials are capable of being property, subject to property rights, at all.

Although something is property only when it is subject to property rights of individuals, only certain entities are potentially to be seen as the subject of property. Cohen contends that "all

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[46] J. Childress , 'Ethical criteria for procuring and distributing organs for transplantation' (1989) Journal of Health Politics, Policy and Law p87

[47] M. Brazier , 'Organ retention and return: Problems of consent' (2003) 29 Journal of Medical Ethics p30

[48] L. Andrews ; 'My body, my property' (1986) p16

[49] In re Organ Retention Group Litigation [2005] QB p506.

[50] Yearworth v. North Bristol NHS Trust [2009] EWCA Civ p37].

[51] K. Campbell , 'On the general nature of property rights' (2001) 2 Theoretical Inquiries in Law p79

external private property is made of something that was once no one's private property, either in fact or morality[52]" But whereas land and most other external physical items can already be seen to be items which are capable of being property, this status is not self-evident with respect to parts of the body. Indeed, example of an item not capable of being property is human biological material. Only if this hurdle can be surmounted can one then entertain the further question whether property rights have been created with respect to such materials, how, and in whom they vest. We shall consider the potentiality of property rights in our own living bodies before considering parts of the human body which have been severed from the whole, and then dead bodies or parts thereof.

Self-ownership is said to be an intuitive and foundational concept to which we all subscribe[53]. For liberal theorists, in particular, there is no tension with regard to human biological materials and notions of property. Cohen has remarked "It is an intelligible presumption that I am entitled to decide about the use of this arm and to benefit from its use, simply because it is my arm"[54].

There are two different arguments at play here. First, that bodies are not simply things. Second, that we should not treat bodies as if they were things. Kluge states that most believe that "people have such a close association with their bodies that to consider bodies and organs as property is tantamount to considering the people themselves as chattels[55]". There may also be an associated anxiety that if one can own oneself, what is there to stop such ownership vesting in another and implying legitimate slaveholding? In Yearworth v. North Bristol NHS Trust, Lord Judge CJ observed that "The common law has always adopted the same principle: a living human body is incapable of being owned"[56].

We consider human body as the whole system of organs and tissues which operate altogether. Here can arise the question when the organ is taken out of the body, then what status does it hold? Radin opines that bodily parts may be too "personal" to be property, and that we have an intuition that property necessarily refers to something in the outside world, separate from oneself.[57]. Penner argues that things that are intrinsically connected to individuals are not potentially the subject of property rights.[58] However, once a limb, organ or sample has been

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[52] G. Cohen , Self-ownership, Freedom, and Equality (Cambridge University Press, 1995), p. 73
[53] P. Cox , 'Body values: The case against compensating for transplant organs' (2003)p 33
[54] S. Coval, J Smith "The foundations of property and property law"(1986) Cambridge Law Journal, p 457
[55] Kluge, Bioethics: An Anthology (London: Blackwell, 2006) p483
[56] Yearworth v. North Bristol NHS Trust [2009] p37

[57] M. Radin , Reinterpreting Property (University of Chicago Press, 1994), p. 41
[58] Penner, The Idea of Property, p. 114.

removed from the body and stored in, say, a sperm or blood bank, it possesses all the attributes of personal property[59]. The conceptual impossibility of separating a particular thing from the person to whom it belongs is the hallmark of personal as opposed to property rights.

As Dickenson remarks "the common law posits that something can be either a person or an object – but not both – and that only objects can be regulated by property-holding[60]"The rules governing each are distinctive in their nature as well as in their protection, both intrinsically and in terms of regulating relationships with third parties including the state. It has been argued that where the material concerned is destined to be replaced in the same, or possibly another, person that laws relating to persons should continue to apply to it. Swain and Marusyk assert that a categorical distinction must be made regarding tissue that is permanently removed from the body as opposed to tissue that is temporarily removed with the intention of having it subsequently become part of the same person.[61] The German Federal Court has determined that a person has property rights in 'their' separated body parts, but that where the parts concerned are destined to be replaced in the person's own body they are not things, and to interfere with them constitutes bodily injury[62]

If we could consider the organs and tissues as property, then the LTHOT will not be needed. The transplantation would be regulated in accordance to Civil law (inheritance). The organ of deceased person would be separated in as many pieces as many relatives the person has in the same line of hierarchy of relatives. Another issue will be the sell of organs. LTHOT prohibits sale of organs and tissues, but if organs and/or tissues will be considered as property, then person could sell it as the property rights are protected by the Constitution of RA.

[59] C. Clarkson and H. Keating , Criminal Law: Text and Materials, 5th edn. (London: Thomson/Sweet & Maxwell, 2003), p. 771.
[60] Dickenson, Property in the Body, p. 4.
[61] Swain and Marusyk, 'An alternative to property rights' p 13.
[62] Bundesgerichtshof, Urteil 9 November 1993, Aktenzeichen VI ZR 62/93. par823

Chapter 4 Armenian approach on transplantation

LTHOT states the main notions of the law and the participants of the act. The alive donor is a natural person who voluntarily gives his/her organs for transplantation. The recipient is a natural person whom an organ for transplantation will be performed.

Article 10 of the LTHOT states that transplantation of alive donor's organs could be done only when:

1. The donor gives consent voluntarily and knowingly in a written form,
2. 15 days before the surgery donor informed about possible negative outcomes and
3. Donor passed a comprehensive medical examination and his/her health condition allows the donation

Article 12 regulates donor's rights only after giving the consent for organ donation. It states that the donor who has already given the consent has a right to demand information on possible negative outcome from the transplantation. Ideally a person should have a right to know about consequences before engaging in transplantation as a donor. This means that the medical institution does not bear fiduciary duties to explain all consequences to the donor and donor gives his/her consent without being informed about possible outcomes. This article does not satisfy the basic legal requirements and it needs to be amended. The provision of "the donor who has given the consent" must be amended to "the person who wants to be a donor".

The LTHOT also states that the list of people who cannot be a donor, especially

1. Minor citizens (under the age of 18)
2. Citizens with disabilities
3. Pregnant citizens
4. Prisoner citizens

The restrictions are made for citizens only. If we apply the law as it is written word by word, then he person, who is pregnant and has no citizenship, could be considered as a donor. The article also needs amendment as to be addressed to all people not only to citizens, because everyone shall be equal before the law.

As for pregnants, minors and people with disabilities the restrictions are made because of their vulnerable conditions, then why prisoners could be donors to their close relatives only? We can imagine a situation, where A imprudently crashed B who is not his relative. Then A has no right to donate his organ or tissue to B. We think that the law can state a close in exceptional

cases to let an imprisoned to donate his/her organ, if an imprisoned fully realizes his actions and gives his/her consent.

As to deceased donors, in 2002 the LTHOT required the opt-in system for organ donation of deceased person. Article 7 stated that donation of organs or tissues from a deceased person could be taken only if the person had agreed before his/her death. The consent of the person was mandatory and the opinion of relatives was not considered anyway. It was the hard opt-in system of consent due to not consideration of relatives' opinion and consent for donation.

In 2009 the amendments of law changed the system from hard opt-in to soft opt-out. Now article 7 states that organs and/or tissues could not be taken only if the deceased person had opted-out during his lifetime. In case of not refusing to be a donor after the death, the organs and/or tissues could be taken with the consent of relatives. If person does not want to donate his/her organs, then he/she has to opt-out according to the procedures described by law. The procedure is not clear at all and very complex for an average educated person to understand and use in practice.

There is a list of relatives who can give or refuse to give organs for donation and their hierarchy.

1. Spouse
2. Adult children
3. Parent
4. Siblings
5. Grandparents

The same article states that from the same level of relatives it is enough to have one's consent for donation.

We can infer from the article 7 that the organs can be taken from a body after the death only when the person did not refuse to be donor after the death according to the procedure described by the Government decision. It means that person loses the right on his body and the right passes to the relatives. As it was discussed that human body and its parts cannot be considered as a property and no one could have ownership rights on others body or its parts. In anyway, the existing regulation violates deceased person's right to decide what to do with his body or its parts.

Article 7 lists the hierarchy and not describes anywhere the means of it. We can infer that the base of the list is moral affection of deceased and his/her relatives. At the first step is the

spouse. The problem is that in Armenia the marriage is legal only when it is registered in accordance with the law. The marriage in the Church or civil marriage is not covered by the law. Spouse giving the consent ideally reflects the wish of deceased. We think that the 1st point can be amended to “Spouse or a person who is in factual martial relations with the deceased”

The other contradiction refers to the age of children and siblings. The law requires that children have to be adult (more than 18 years old) but there is no such a restriction for siblings. Being adult is a mandatory requirement for being sure that the person realizes what transplantation is and can judge the situation and understand the consequences. The 4th point needs amendments as well as follows” adult siblings”

The law states that from the same level of relatives it is enough to have one’s consent for donation. This provision is not fair to the contradicted opinions of the same level relatives. For example if a person has 3 children, one gave consent but two others refused, then their rights will be violated, especially right of family and private integrity. It will be better to state that the organs could be taken if all members of the same level of relatives give unanimous consent for donation.

We think that the regulation of LTHOT was better in 2002 and was more corresponding to the Constitution. The Constitutional Court has a decision[63] on the article 7 of the LTHOT, where it finds that article 7 contradicts with the article 3 and 14 of the Constitution in the way that transplantations are not actualized in the RA. After this decision there were no amendments in the article. This decision gives a wide room to interpret it. We will discuss the contradictions with the Constitution of 2005 and 2015 including more articles.

Article 3 of Constitution 2005 states that the human being, his/her dignity and the fundamental human rights and freedoms are an ultimate value. The state shall ensure the protection of fundamental human and civil rights in conformity with the principles and norms of the international law. The state shall be limited by fundamental human and civil rights as a directly applicable right. Article 14 of Constitution 2005 states that Human dignity shall be respected and protected by the state as an inviolable foundation of human rights and freedoms.

The meaning of dignity is very wide and has been interpreted in many ways. It can be described as an individual or group's sense of self-respect and self-worth, physical and psychological integrity and empowerment[64]. By saying physical integrity, we mean person’s body as well as its parts, e.g. organs, tissues, hands etc. At the philosophical level, following

[63] ՍԴՈ 913, ՀՀՊՏ 20100922/45(779), ուժի մեջ է մտել 14.09.2010
[64] http://www.duhaime.org/LegalDictionary/H/HumanDignity.aspx

Kant, the expression human dignity is used to indicate that persons should always be treated as ends in themselves and never merely as means. Kant presents "dignity" as exactly the opposite of "price": while "price" is the kind of value for which there can be an equivalent, "dignity" makes a person irreplaceable[65].

The obligation to respect one's dignity must not force only during his/her lifetime. Dignity should be respected after the death as well. Civil Code of RA[66] article 20 states the legal capacity and capability as follows: the ability to have civil rights and bear duties (civil legal capacity) is recognized in equal measure for all citizens (this is a legal capacity). The legal capability of a citizen arises from the time of his birth and is terminated by death. At the same time Criminal Code of RA[67] articles 265 and 383 state that outrageous treatment of a dead body or a burial place, destruction, damage or desecration of cemetery facilities or items, or places allocated for memorial ceremonies and t heft of items from the dead and wounded in the battlefield are offences. From the above mentioned we can conclude that civil rights and obligations are terminated after the death, but the fundamental rights such as respection of dignity stay with person even after the death.

Taking organs from deceased body is a way of intervening to the physical integrity. In RA the only authority (body) that can process the donation is a qualified medical center that has a license given by the State. Comparing the above mentioned, we can conclude that taking organs from deceased person's body without his own consent is a violation of articles 3 and 14 of the Constitution.

Article 15 of the Constitution states that everyone has a right to life. The right to life is related to the right to die; the right to physical integrity goes beyond the living body, it achieves the dead body; man's domain is not only over living body, man's domain over his body follows the corpse. The LTHOT differentiates the consent of alive person from the consent of deceased. In the first case the consent must be given knowingly and voluntarily. For deceased the consent is presumed. It means that the law has discrimination assessment of consent. The discrimination is prohibited under the article 14.1 of the Constitution. It states that any discrimination based on any ground such as sex, race, color, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth,

[65] http://www.cs.mcgill.ca/~rwest/link-suggestion/wpcd_2008-09_augmented/wp/h/Human_dignity.htm
[66] The Civil Code of RA, ՀՀՊՏ 1998.08.10/17(50),in force since 01.01.1999
[67] The Criminal Code of RA, ՀՀՊՏ 2003.0502/25(260),in force since 01.08.2003

disability, age or other personal or social circumstances shall be prohibited. From this prospective presumed consent contradicts with article 14.1 and 15 of the Constitution.

Article 17 of the Constitution states that no one shall be subjected to scientific, medical and other experiments without his/her consent. Experiments differ from the transplantation surgery, but anyway, it deals with the physical integrity of the person. If in the experiment case the explicit consent is needed then why the consent is not needed for donation? We found that the LTHOT does not comply with the Constitution. Article 6 of the Constitution states that the Constitution has supreme legal force. The laws shall conform to the Constitution. In case of contradiction between Constitution and the law, the norms of Constitution prevail. We found, that the contradiction exists in determining the consent, so the explicit consent system shall prevail.

On the other hand, the article 127 criminal code of RA[68] states that doing medical experiments without consent of the patient is an offence. Article 132 states that taking organs and tissues from a person are within the scope of trafficking. In our understanding taking organs from a person means that the action was performed without prior consent. So, taking organs from deceased person even with the consent of relatives constitutes the offence, because the person did not give his own consent.

According to amendments of Constitution 2015, article 3 states the human being shall be the supreme value in the Republic of Armenia. The inalienable dignity of the human being shall be the integral basis of his rights and freedoms. The dignity perceives inviolable. The dignity and physical/ moral rights are separated now. Article 25 states that everyone shall have the right to physical and mental integrity. The right to physical and mental integrity may be restricted only by law, with the aim of protecting state security, the public order, health and morals, and the fundamental rights and freedoms of others.

From all of the mentioned gaps, we think that the law needs to be amended in the way described in the paper and to get back to the system of opt-in. This system is more suitable for Armenian legal system and does not contradict with the Constitution. We think that person, his dignity, physical and moral integrity as well as his/her consent is the values that each country must protect.

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[68] ՀՀ Քրեական օրենսգիրք ՀՀՊՏ 2003.05.02/25(260) , ուժի մեջ է 01.08.2003

Conclusion

As was described, countries have to choose one of two default policies either presumed or explicit consent system. In presumed-consent states, people are organ donors unless they register not to be, and in explicit-consent countries, nobody is an organ donor without registering to be one. This is not strictly accurate, as we have seen. Whilst a failure to object in a presumed consent system triggers a presumed willingness to donate. Informally, such silence reflects passive willingness; one can make no generalized assumption in this regard. Formally, though, it is a decision to leave the matter to relatives after death, in so far as in opt-out system relatives may, usually in a hierarchical order, they consent to donation after the death.

We may, however, query why, if a failure to object under a presumed consent model is capable of being evidence of a decision to donate, the failure to consent to donation during life is not viewed in explicit consent systems as a decision not to donate. The consent from relatives the next step in such situations. Although it is unclear that some people who do not make a definite decision to donate whilst alive are nonetheless still willing to donate, this does not explain why relatives are permitted to consent to donate on the deceased's behalf even where they have no evidence that this is what the deceased would have wanted. If consent is an action then it has to be performed by the person who gives it. The action could not be presumed.

The role of relatives has therefore typically been as default decision makers. Den Hartogh observes that:

"The fact that next of kin are granted the right to decide in so many countries, sometimes contrary to the statutory regulations, is not based on an adequate moral justification but on the sole fact of their presence on the scene and the special consideration for their circumstance required at that moment"[69]

But such pragmatism cannot ethically ground personal decision-making powers. Where relatives are permitted to object in their own right under a presumed consent system, on the other hand, this is a concession to potential severe distress as opposed to recognition of a broader decision-making role. There may be some who do indeed consider that relatives possess their own discrete decision-making authority in relation to deceased individuals, and who cannot therefore comfortably accommodate presumed consent at all. In presumed consent, the donor

[69] Den Hartogh, Farewell to Non-commitment p 67.

does not give a consent (does not give his organs) for donation. The authorities take the organs from deceased's body.

Saying in more informal words, person could not anticipate the end of his/her life (the death) to register his/her unwillingness to become a donor. In any case, it is easier and more fair for donor's side to give his/her consent and register it according to the procedure described by the law.

As it was described in the paper, Armenian approach is not ideal and needs some amendment in the existing regulation and , we think, that shifting from opt-out system to opt-in will be more fair and in conformity with the scope of the legislation. If the changes will be performed there will be need to inform population and work on the level of legal education.

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