

The legal and ethical framework governing Body Donation in Europe – 1st update on current practice

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SUMMARY

Previously, we have reported on the legal and ethical aspects and current practice of body donation in several European countries, reflecting cultural and religious variations as well as different legal and constitutional frameworks. We have also established good practice in body donation. Here we shall further extend the legal and ethical frameworks in place and also focus on novelties in the law

and different directives. Of particular interest are points that address the commercialization of human bodies and body parts and weaknesses in the legal directives. Therefore, it is important to define what is ethical and what needs to be considered unethical in body donation and the subsequent utilisation of human bodies for teaching and research.

Key words: Body donation – European Community – Legal and ethical aspects

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INTRODUCTION

In an initial paper, the Trans-European Pedagogic and Anatomic Research Group (TEPARG) summarized the current practice of body donation throughout Europe (McHanwell et al. 2008). Since then, several legal and ethical laws and directives regarding body donation and the use of human bodies for teaching and research have been published throughout. Accordingly, an update is needed. Here, we shall focus on the novelties introduced. This is also to give an update on current practice and -hopefully to help- in the harmonization of the use of cadavers for the anatomical sciences.

PERSPECTIVE FROM AUSTRIA (PROFESSOR E. BRENNER)

Based on the doctoral thesis by Elisabeth Mayer, the Austrian – and with this also to some extent the European – legal and ethical framework can be updated (Mayer, 2010).

In general, using a human cadaver in medical education and research can be classified as a crime; the act of violation of a (human) cadaver (§ 190 Abs 1 StGB). There are therefore grounds for legal and ethical justification; namely the consent of the deceased during his/her lifetime (bequest). Furthermore, legal rules governing the handling of cadavers and/or their disposal may be consulted. These federal state laws, as described in (McHanwell et al., 2008), may contain regulations, which allow municipalities to hand over the cadaver to an anatomical department when the person(s) who are in charge of the care of the cadaver failed to take precautions for the funeral. Within Austria, such legal provisions can be found in Burgenland, Carinthia, Lower Austria, Upper Austria, Salzburg, Styria, Tyrol and Vorarlberg. Only the Viennese Law does not provide appropriate articles. In Vorarlberg, relatives are also allowed to hand over the cadaver to an anatomical department.

The Bequest

The main question is: who holds the (exclusive) right of disposal for a cadaver, its parts or ashes? This is important in two aspects: first, it is only a criminal act to divest the holder of the right of disposal of the cadaver; secondly, it is not criminal act when the holder of the

right of disposal agrees. Thus, who is the holder of this right?

Basically, the holders of the right of disposal are the deceased persons themselves. This means that anybody may stipulate during her/his lifetime what should happen to her/his cadaver. Thus, she or he can specify that the cadaver should be handed over to an anatomical department.

It is now debatable where this right of the deceased results from. As legal background, the material law does not come in consideration anyway, because the body of a living human being and the parts solidly interconnected with it are not issues according to the classic division in the civil law but belong to the person. Furthermore, it is not within the framework of hereditary disposal, because the body of a person does not belong to his/her personal fortune. Also, family law cannot be used, since this requires the existence of a relationship to another human being - and not to one's own body. According to ruling opinion, the right to be able to bequest one's body after death while still alive, emerges from general personality rights.

The Austrian personality right is based on article 16 of the Austrian General Civil Code. This article, enacted on January 1st, 1812, reads: *“Everyone has innate rights, already obvious by common sense, and is therefore regarded as a person. Slavery or servitude, and the exercise of power related to these rights is not permitted in these countries.”*

This regulation can be compared to the German general personality right, articles 1 and 2 of the German Basic Law (German constitution; “§ 1 (1) *Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority.* (2) *The German people therefore acknowledge inviolable and inalienable human rights as the basis of every community, of peace and of justice in the world.* (3) *The following basic rights shall bind the legislature, the executive and the judiciary as directly applicable law.* § 2 (1) *Every person shall have the right to free development of his personality insofar as he does not violate the rights of others or offend against the constitutional order or the moral law.* (2) *Every person shall have the right to life and physical integrity. Freedom of the person shall be inviolable. These rights may be interfered with only pursuant to a law”*. This formulation was developed in 1954 by the Federal Court of Justice.

Another – binding – regulation is the Charter of Fundamental Rights of the European Union (European Parliament Council Commission 2007), issued in 2007 and enacted by the entry into force of the Treaty of Lisbon on December 1st, 2009. This Charter only applies to EU member states, but binds them to act and legislate consistently with the Charter.

Actually, the legal capacity of a person finishes with is/her death, and the question arises as to whether and how the previously formulated disposal arrangements of the deceased should be obeyed. The federal state laws dealing with corpses and their burial can be related in this context. It is possible to find regulations, whereupon the type of burial must follow the will of the deceased and post-mortems are at the disposal of the deceased. From these regulations one can deduce that the will of the deceased is of basic importance. This opinion can also be found in the theory of so-called post-mortal personality right. In Austria and Germany, it is today acknowledged that the once existent personality right continues after the death of its bearer. This construction is not unknown in other areas of Austrian law: Just like the will of the testator has to be followed after his/her death, his/her work also enjoys protection after the death of the originator (copyright-legislations). Post-mortal organ-removal (for transplantation purposes) cannot take place if the deceased has voiced disagreement while alive. This shows that personality protection does not finish with death. The deceased therefore has not only the right to make a disposal; such a disposal also has to be followed. After the deceased person can no longer enforce her/his wishes her-/himself, someone else must take care of the cadaver. This is the so-called guardian of the corpse; this is the person who is incumbent on the custody for the burial. This person must enforce the disposal(s) of the deceased.

If a disposal is made of a person's body while alive no special form must be kept. For forensic reasons, a (written) explanation of the wishes regarding the contact with and procedures to the corpse should be made in the framework of a legacy. If no (explicitly written) declared will of the deceased is available, his/her conjectural will must still be heeded;

this for reasons of piety and because of the post-mortal personality right.

Restriction with the exertion of the disposal-right

Not significant is either the declared or the conjectural will of the deceased, when it comprises actions in reference to the body, which are against piety. Is in the long run the interest protected by the law. Therefore those disposals that the deceased made during his/her lifetime are subjected to ethical limitations. In most cases, these ethical aspects are already subject to specific laws, which represent the lawful framework for contact with the body. There are, however, also forms of applications of the body, whose admissibility does not emerge from these laws, but which however, from the viewpoint of piety, appear completely harmless, and even ethically valuable. One should consider a disposal in which the deceased allows the use of his/her corpse for the manufacture of medications. This will help the health of others. In contrast to this, it would be unsavoury, if the corpse were used for the manufacture of cosmetics, for example soaps, as the application of corpses or their parts for the production of mere commodities is not desirable from an ethical point of view. Such purposes injure the general feeling of piety. Whoever contravenes such a disposal cannot rely on the consent of the deceased and is therefore punishable.

It is questionable how a disposal should be evaluated when payment was asked by the deceased to allow a generally piety-appropriate form of application of its dead body. For example, after death the deceased made his/her body available to a research-institution in exchange for payment of a certain amount of money. According to some of the literature, piety-adverseness is to be assumed if a disposal serves the satisfaction of a dishonest feeling or is interconnected with the intent to make a profit. First, it must be clarified whether the payment-related leaving of the body is interconnected with a profit intent. On this occasion, the two concepts of payment and profit have to be distinguished. A business is payment-like if an economic balance should be scored. A payment-like business is completed with profit-intent, when the revenues should not only cover the expenses but should result in a surplus. A bare compensation for expenditures therefore represents no profit.

Incredibly, however, it appears that expenditures for which the deceased should be compensated are interconnected with the granting of consent. Leaving of the body against payment therefore equals a sale with profit intent and represents an injury of the piety. However, it is not the whole disposal that is adverse to piety, but only the payment character. Application of the body in research and education represents a purpose consistent with piety. The wish of the deceased- e.g. that his/her body might be made available for a research institution, is therefore to be respected. Payment alone injures the piety, because the body should not be degraded to an object of trade.

PERSPECTIVE FROM FRANCE
(DOCTOR O. PLAISANT)

In recent times, no new legal procedures relating to body donations for anatomical examination have been enacted in France. Consequently, the account given in our previous paper (McHanwell et al., 2008) remains valid. The only directly applicable legal framework that may be taken as applying specifically to body donation for anatomical purposes is enshrined in Article R2213-13 of the “Code Général des Collectivités Territoriales”. There is no general regulation for body bequests to this day and each body donation centre has its own regulations. However, since the first version of our paper (McHanwell et al., 2008), the centre for body donation in the University of Paris Descartes is no longer charged financially, except for the transportation of the body.

The status of the body is written in the Civil Code and guaranteed by the Penal Code and the principles of indivisibility of the human body, its respect, its non commerciality, the need for informed consent for each donation and the protection of genetic patrimony were confirmed by a decision of the Constitutional Council in 1994.

In 2009, the exhibition “Our Body” came to Paris (12 February 2009-10 May 2009) after appearing at Lyon and Marseille. Two associations, “Ensemble contre la peine de mort” and “Solidarité Chine”, decided to take the exhibition organizers to court. The court ruled by banning the exhibition (21 April 2009).

The court of appeal subsequently confirmed the decision (30 April 2009), in light of the principle of non-commerciality and because of the unknown origin of the bodies. Finally, the *Court de cassation* (2010) confirmed the rulings: -According to Article 16-1-1, Paragraph 2, of the Civil Code, ..., the remains of deceased people should be treated with respect, dignity, and decency- and -exhibitions of cadavers for financial gain contradict this requirement-, this decision follows the recommendations of the *Comité Consultatif National d’Ethique* (Avis du CCNE, 2010).

PERSPECTIVE FROM GERMANY
(PROFESSOR F. PAULSEN)

There have not been any new legal procedures regarding body donations in Germany. Thus, the contents of the former paper (McHanwell et al., 2008) are still valid in Germany. However, the Anatomische Gesellschaft is just preparing a new survey to collect further information about possible changes in Germany. Data from this survey are expected for 2013.

As several members of the Anatomische Gesellschaft have obtained e-mail advertisements during the last month from some firms selling anatomical specimens on the international market the Anatomische Gesellschaft has made a statement with regard to this practice (<http://www.anatomische-gesellschaft.de/77-startseite/124-stellungnahme.html>):

Anatomy deals with the structure of the human body. For students of medicine and doctors a profound knowledge of anatomy is essential. It is most suitable to use the human body after death for studying anatomy, for instance in the dissection course during medical education and in training courses for surgeons and doctors in disciplines such as radiology. Many individuals donate their bodies after death to the institutes of anatomy to ensure medical education and clinical training.

In Europe and in many other countries worldwide the donation of the body is regulated in a specific legacy. The body donor asks an institute of anatomy, mostly in a university closely located to the donor’s place of residence. It is defined how the body of the dead individual is transported to the institute of anatomy and how the funeral of the body is organised after its use for education and training. Some institutes of anatomy ask the donors

to contribute to the costs of the funeral. Furthermore, the specific legacy contains the donor's agreement or objection to the preservation of parts of his or her body as permanent specimens for the anatomical collection. These parts of the body are then not buried.

The Anatomische Gesellschaft, the organisation representing the institutes of anatomy and the scientists working in anatomical research, has a clear-cut principle, which is indispensable for using anatomical specimens: the body donor must agree to the donation on a purely voluntary basis, and this agreement has to be set forth in the written legacy. The origin of the specimens must be provable conclusively.

The Anatomische Gesellschaft is worried by the growing practice of selling anatomical specimens on the international market. These specimens often have their origin in countries in which the jurisdiction and ethical views concerning body donation differs from European standards. This distribution of anatomical specimens is irreconcilable with a trustful relationship between the body donor and the anatomical institutes.

The Anatomische Gesellschaft asks scientist, teachers of anatomy, students and the interested public to disapprove of the trading in anatomical specimens. It must be a principle that specimens are only taken from body donors who have agreed in a written specific legacy in favour of anatomical research and teaching.

PERSPECTIVE FROM ITALY (PROFESSOR R. DE CARO)

In a preceding paper (McHanwell et al., 2008), Prof. Mazzotti from the University of Bologna referred on anatomical education in Italy. At present, the Italian debate about body donation is still ongoing and new legal proposals have been presented. Thus, the Italian situation about anatomical education with donated bodies and/or body parts will be outlined here, together with our personal experience in the Department of Human Anatomy in Padua.

The University of Padova has played a pivotal role in the history of Anatomy. In 1543, Andreas Vesalius, while Professor of Anatomy at the University of Padova, published his masterpiece *De humani corporis fabrica*, which is universally considered to be the beginning of modern anatomy and medicine. With respect to his predecessors, Vesalius, a Renaissance

anatomist, descended from his chair and carried out dissections with his own hands, believing that the direct observation of the human corpse was the basis of anatomical knowledge. Almost all the most important anatomists of the 16th, 17th and 18th centuries taught anatomy in Padova. Here, the first permanent theatre ever designed for public anatomical dissections was also built, in 1594, under the supervision of Hieronymus, thus revolutionising the teaching of anatomy.

Although it is true that a specific law regarding body donation is not present in Italy, we must consider that some references clearly permit the use of cadavers for anatomical dissection and, in some Italian Universities, anatomical dissections are still performed according to these rules. The possibility of using corpses for medical education and scientific research is expressly provided for in Article 32 of "Regio Decreto" no. 1592 of August 31 1933 about University Education, which states that: "cadavers [...] whose transport is not performed at the expense of relatives up to the sixth degree or by confraternities or associations who may have made commitments for the funerary transport of associates and those [cadavers] coming from medico-legal investigations (apart from suicides) and not claimed by relatives in the family group, are reserved for teaching and scientific study". A further reference to the use of corpses for medical education and scientific research is also present in the Regulation of the Mortuary Authorities (Decree of the President of the Republic no. 285/1990), which specifies that: "delivery to the university Anatomical Institutes of cadavers [...] for teaching and scientific study must occur after the period of observation prescribed [...]" (Art. 40) of 24 hours after death (Art. 8). In addition, "the acquisition and conservation of cadavers and anatomical specimens, including foetal material, must be authorised from time to time by the Local Health Authority" (Art. 41) (De Caro et al., 2009).

Although possible from a legal point of view, anatomical dissections for medical education have become quite rare in Italian Universities because of a decision taken by the Italian Government in 1970 to allow free access to medical school admissions for applicants in their first year. The effect of this policy was that there was an enormous increase in the numbers

of students in the medical schools. As a consequence, many dissecting room facilities were closed in order to allow the building of larger lecture theatres to accommodate the additional student numbers and it was no longer possible to undertake gross anatomy in the conventional way using bodies or prosections. In the following years there was a consequent and progressive loss of staff able to teach gross anatomy using the human cadaver. In recent years, Italian medical schools have introduced limitations to University access, with a reduction in the number of students. Thus, currently it is possible to restore gross anatomy teaching programs involving dissections on human bodies. This proved quite difficult in many Italian Universities where dissecting rooms and medical staff with experience in dissection are no longer present. However, the Italian Society of Anatomy and Histology and the Italian College of Anatomists wish to restore a more complete gross anatomy teaching program involving dissection. Italian anatomists and surgeons believe that training on cadavers should be part of the preparation of all surgical specialists.

For instance, the Veneto Region has recently given an economic contribution for the training on cadavers of orthopedic residents.

The Department of Human Anatomy and Physiology of the University of Padua developed a specific program of donation of the body for teaching purposes and dedicated two rooms of the building to anatomical education through dissection. Although the above-mentioned laws do not take into account the wishes of the deceased, we decided to accept, in analogy with Italian regulations covering organ donation for transplantation (Law 91/1999) and cremation (Law 130/2001) and European guidelines, only the corpses of people who made an explicit declaration of donation of their bodies for anatomical education during their lifetime. Moreover, in the procedures of our Department the relatives are also asked to sign a consent form in which they accept the wish of the deceased. In analogy with Art. 23 of Law 91/1999, the relatives making such declarations are the non-separated consort, common-law consort or, in the absence of the above persons, children of age, parents, or legal representatives. The above declarations by the deceased and relatives are given to the Local Health Authority for authorisation. The principles, stated in the Constitution of the Italian

Republic (1948) for the promotion and development of scientific and technical culture and research (Art. 9) and health safeguards as an individual's fundamental right and for collective benefit (Art. 32) may also be considered at the basis of body donation for anatomical education (De Caro et al., 2009).

So far, the Department of Human Anatomy and Physiology has received many declarations of wishes to donate bodies and anatomical dissections are performed on donated anatomical material. We have also been directly involved in the dissemination of information about the principles and procedures of body donation and through the mass media and dedicated meetings, with particular attention to the ethical aspects.

In our experience, an integrative source for dissection may also be represented by body parts resulting from surgical procedures. In clinical practice and the scientific literature, donation of surgical tissues from the living has mainly been considered for research purposes, but its teaching potential is still underexploited. The Department of Human Anatomy of the University of Padova, in formal agreement with the Hospital of Padua, has also integrated its anatomical programme with limbs or parts of limbs amputated in the surgery departments. Patients are informed about the possibility of donation by the surgeon or, if they request further information, by the anatomist responsible for the donation programme; if they decide, they sign a consent form. Body parts are easier to manage, as they can be stored frozen and occupy little space. Anatomical education to medical students or residents is frequently shared with the surgeons who follow the patients clinically (Macchi et al., 2011). The program of anatomical education through donated bodies and parts of bodies of the Department of Human Anatomy of Padua also achieved official ISO 9001:2008 certification in 2011.

As regards the most recent legal proposals, we must remember that in 2004 and in 2007, the Italian Parliament had presented two specific law proposals concerning the donation of bodies for anatomical education and research, which would have created regional centres where such bodies could be prepared and studied. These laws were discussed but they were not approved. Further similar legal proposals were presented recently and in October 2011

they were unified in a unique proposal in discussion at the Italian Parliament. This law would permit potential donors to express in life a wish to donate their bodies after death for anatomical education and research. Relatives will not be allowed to consent to donation after death without a preceding expression of the deceased. Bodies will be allowed to be retained for no more than one year after which they must be disposed of.

PERSPECTIVE FROM MALTA (PROFESSOR I. STABILE)

Malta has a long and distinguished history related to Medicine. The first documented reference to Malta's involvement in healthcare dates back to the 14th century with the founding of the Santo Spirito Hospital in 1347. Following their arrival in Malta, the Knights of St John opened the Sacra Infermeria in 1574 which was considered to be one of the best hospitals in Europe. The services offered were further enhanced when a school of Anatomy and Surgery was inaugurated in 1676 by a decree of the Hospitaller Order of St John's Grand Master Fra Niccolo Cottoner.

The Malta Medical School has a three-century continuous history of excellence in the field of medical education being formalised as a university faculty by Grandmaster Fra Manuel Pinto de Fonseca in 1771. This makes our Medical School one of the oldest in the world. The coming of the British in 1800 resulted in our University being run along English academic lines, a system which has been retained up to the present day.

Nevertheless, there is no specific law in Malta that permits teaching or research institutions to accept bodies from donors. In the absence of specific legislation, the Department of Anatomy at the University of Malta has developed a good relationship with the British Residents Association to which most British expatriates belong. Potential donors are provided detailed information about the donation by a departmental representative. Thanks to the generosity of these individuals, the Department is fortunate to receive approximately 12 to 15 cadavers each year. Volunteers record their intentions by adding a codicil to their will which is witnessed by a Notary. The wishes of the donor cannot be overridden by

their families after death. In practice however this codicil is of little value, as the will is usually accessed some 2 to 3 weeks after death, whereas our hot climate requires that the cadaver be transported to the Department of Anatomy for embalming as soon as possible, and certainly within 24 hours of death. In order to overcome this limitation, the Department requests that in addition to the codicil, the donor should also indicate their willingness to donate their body in the form of a letter which should also include the contact details of the next-of-kin and their family doctor (as s/he will be required to issue the death certificate). Donations are free, and no payments are made to donors or to their relatives.

Upon death there is no need for further notification to a higher authority, nor is a certificate required to confirm that the donor was free of known infections prior to death. Following the confirmation of death by a medical practitioner, the body is transported (by undertakers) to the Department of Anatomy, together with the death certificate. Over the years a variety of embalming methods have been used, most recently the Thiel technique. Once adequately embalmed, the body is usually stored at 4°C until needed. Although the majority of cadavers are used by students undertaking their anatomical project (see below), the Department is increasingly being asked to run postgraduate surgical courses, thus increasing our reliance on cadavers.

Although student numbers have more than doubled from approximately 70 per year only 5 years ago (primarily due to the influx of international students), and in spite of a radical overhaul of teaching, the use of prosected specimens remains at the core of the Department's didactic approach to the teaching of anatomy. Although there is no specific dissection course during the basic science years of the medical course, students are required to undertake a project during the summer between the first and the second year of study. Donated cadavers are divided into sections and students are required to select a dissection project from a list prepared by the Department to replace prosections that are no longer useable for teaching. Students prepare these prosections under the supervision of one of the members of the Department. Although the student projects are intended to integrate active learning, teamwork and problem solving into our

undergraduate medical education, they also contribute significantly to the department's prosected teaching material. As there is no legal time limit for the storage of anatomical specimens, the continued use of cadavers, or parts of cadavers, will largely depend on their condition. Well-preserved prosected material may be retained for several years.

Faculty and staff at the Department of Anatomy are aware that the cadaver also represents a student's first patient, a valuable dimension to learning that helps students gain respect and responsibility and provides opportunities for them to learn in the integrated biomedical, socio-behavioral and clinical contexts in which all patients live their lives. Hence all Year 1 students are informed at the start of the academic year (and this is reinforced regularly) that they must show respect for the cadavers upon which they receive instruction.

Once the prosected material is no longer useable for teaching, the remains are interred in an unmarked grave at the local cemetery, as cremation is not available on the island. Potential donors are informed of this. The University is required to meet all burial expenses.

Two religious services are held each year, organized by the Department of Anatomy with the help of Roman Catholic clergy. These coincide with the feast of Our Lady of Sorrows (the week before Good Friday) and Old Souls Day. All Year 1 and 2 medical students are expected to attend and encouraged to be involved by contributing words or music to the service. The services are generally well attended by the relatives of donors, tutors and students of all faiths.

In conclusion, there is no legal framework for the specific regulation of body donation in Malta. The wishes of the donor are paramount and must be expressed specifically in writing prior to death. Due to the increase in student numbers, the Department has just invested in plastination techniques in the hope that well prepared specimens will last much longer and serve as ideal tools for teaching human anatomy.

PERSPECTIVE FROM THE NETHERLANDS
(DOCTOR. S.BOLT, PROFESSOR P.O. GERRITS)

Research on body donation in the Netherlands

The data provided in this update are based on cooperation between research of the

anatomical institute of the University Medical Center Groningen (UMCG) and a PhD research on body donation at the Radboud University Nijmegen.

Body donation in Dutch law

The first time dissection of a corpse was legalized in the Netherlands was in 1555 when King Philip II allowed the Amsterdam surgeons' guild to perform dissection on one body per year (IJPma et al., 2009). Anatomists struggled with a severe scarcity of bodies to dissect and often the bodies of executed criminals were used. Before 1555, several Dutch sources mention that bodies were even stolen from graves and gallows (Hansen, 1996). But criminals were not the only subjects used for dissection: the unclaimed bodies of poor people who died in city hospitals or in the poor quarters of the cities were also regarded as suitable for dissection (Huisman, 2008). Despite the scarcity of bodies, in the seventeenth century the anatomy in the Netherlands was flourishing which is well illustrated by many Dutch painters, such as Rembrandt van Rijn's famous painting *Anatomy lesson of Dr. Nicolaas Tulp*, 1632, picturing an anatomical dissection of an executed criminal in Amsterdam (Bolt, 2009), and Jan van Neck's *Anatomy lesson of dr. Frederick Ruysch*, picturing an oversized newborn child, still connected to the umbilical cord and placenta (Hansen, 1996).

The first time dissection of a corpse was mentioned in Dutch law was in the Funeral Act of 1869. This law stated which people could demand the dissection of a body and prescribed that people could also bequeath their body for dissection in a will. Dissection could only find place with the permission of the mayor. Punishable by law were those who performed dissection without being or without the supervision of a medical doctor (*Staatsblad van het Koninkrijk der Nederlanden*, jaargang 1869). Although a will is already mentioned in this law, it was not until the twentieth century and in particular after the Second World War that the concept of voluntarily body donations became more and more rooted in the Dutch society. In 1955, the Funeral Act was adopted in the *Wet op de Lijkbezorging*; the Burial and Cremation Act. The regulation on dissection in this new law did not change much. There was only an editorial change which placed emphasis on the

interpretation of dissection as a final destination (Van der Haar, 1964). In 1968, another significant amendment to the law was made, dissection was now regarded as an alternative way of body disposition (Van Kinschot, 1969). The last significant addition regarding body donation to the Burial and Cremation Act dates from 1991 when in article 67 it was emphasized that human corpses can only be dissected “in the interest of science or scientific education” (Van der Putten, 1992).

In the current Burial and Cremation Act, the regulations on dissections read: a corpse can be disposed of by burial, cremation or an alternative way of body disposition. Article 67 discusses the alternative way of dissecting a corpse in the interest of science or scientific education. Dissection can only take place when the deceased have bequeathed their bodies for this purpose. It will occur according to the wish or the presumptive wish of the deceased. People aged 16 and over can make a last will, either by a notarial act or a handwritten, dated and signed declaration. In the absence of a will, in the article is written down which people can be authorized to destine the body for dissection as well. Article 68 prescribes that dissection can only take place with the written permission of the mayor, which has to be issued free of charge within three days and has to mention the place of dissection. Within 24 hours one can lodge an appeal against the permission. Article 69 prescribes that dissection will not start before 36 hours after death. And dissection will not be performed without the supervision of a medical doctor (Rijksoverheid, 2010).

Since dissection is regarded as a lawful final destination, within the meaning of the Dutch law there is no necessity to treat the remains of dissected bodies as corpses anymore. Therefore, when the anatomical institutes dispose of the remains of body donors they are not obliged to apply the standard body disposition regulations (Van Strijen, 2009). Despite this, every Dutch anatomical institute has chosen to officially cremate the body (parts) in a human crematorium. The Dutch law prescribes that by the acceptance of a corpse for dissection the anatomical institutes are obliged to pay the costs for the final disposition of the remains (Van der Putten, 1992). Each institute collaborates with its own undertaker and crematorium to dispose of the human remains. When the body or its

parts are no longer of use to the anatomical institutes they are stored in coffins until the final cremation in the crematorium. In the past most crematoria scattered the ashes of body donors on a field for that purpose on their property. Environmental legislation, however, foreclosed the overloading of these fields with the scattered ashes of body donors, which are more voluminous and chemical than the ashes of non-donors. Only the crematorium in Maastricht is still scattering the ashes on their own field, the other crematoria have subcontracted a company, named Aqua-Omega to scatter the ashes, during a collective scattering, in the North Sea (Bolt and Venbrux, 2010).

To bequeath their body people need to have a handwritten and signed contract, a will, with one of the anatomical institutes. The body donor contract is tied to a particular institute, so if you sign a contract with the institute in Nijmegen, your body will go there after death. However, Dutch law permits a dissected body to be given to another party if by this means the wish of the deceased to be dissected in the interest of science or scientific education can be realized (Van der Putten, 1992). Therefore, in case of shortage, bodies have sometimes been exchanged between the Dutch anatomical institutes. The question then arises as to how far the law permits body donation across borders. In theory, we did not find regulations in the law that forbid the exchange of dissected bodies to anatomical institutes abroad as long as by this means the wish of the deceased is fulfilled and they will be dissected in the interest of science. In practice, the exchange of dissected bodies with anatomical institutes across the borders has rarely occurred.

Regulations within the anatomical institutes

The Dutch law leaves it open to the anatomical institutes to adopt their own internal rules and formal procedures (Van der Putten, 1992). Dissection is performed by anatomical professionals of anatomical institutes, usually in the basement of the Dutch academic hospitals (Erasmus Medical Centre Rotterdam, Leiden University Medical Centre, Academic Medical Centre Amsterdam, VU University Medical Centre Amsterdam, Radboud University Nijmegen Medical Centre, University Medical Centre Groningen, Maastricht University Medical Centre, and University Medical Centre

Utrecht). Body donors are not actively recruited; therefore to gather information people need to contact one of the institutes that locally administer the body donor registrations (Bolt et al., 2011b). Some of the institutes have a restriction on their registrations, such as a temporarily registration stop to prevent a surplus of bodies (Wijbenga et al., 2010), an age limit to stimulate younger people to register as organ donors (Bolt et al., 2011b), or a geographical demarcation with postal codes to decrease transport costs and the number of registrations.

The anatomical institutes do not guarantee the acceptance of a corpse. First of all, the body has to arrive within 24 hours at the anatomical institute in order to preserve the body. Therefore prospective body donors are advised to inform relatives, friends and the family doctor about their decision. Some other reasons for rejection, which are also locally determined, are: death abroad, severe damage to the body (accident, autopsy), severe obesity or being underweight, contamination with a contagious disease, or severe burns. Organ donation can also be a reason for rejection. Only the anatomical institute in Groningen accepts the so-called total donor; people who donate both their organs as well as their whole body (Bolt et al., 2011a). The institute of the VU Amsterdam makes acceptations for donations to the brain bank and the anatomical institutes of Leiden and the AMC Amsterdam permit the donation of corneas in combination with whole body donation. Due to uncertainty about the acceptance of the corpse, the institutes advise registered body donors not to terminate their funeral insurance (Bolt et al., 2011a). After acceptance, the institutes in Nijmegen, Utrecht, Rotterdam and Groningen test the bodies for contagious diseases such as HIV and Hepatitis B and C. If they are contaminated, these bodies will be taken immediately to the crematorium. For example, the institute in Groningen had to cremate instantly 11 bodies (11.8%) of the total incoming bodies in 2010 after a positive blood test. Besides the cremation costs, most anatomical institutes also pay the transport costs of the corpses from the place of death to the anatomical institutes. Costs raise concerns due to the relatively remote geographical location of Groningen and the fact that funeral insurances cover the transport costs made the anatomical institute in Groningen decide to charge these costs on the donors.

The anatomical institutes preserve the bodies by the technique of embalming, freezing or plastination. Each of the anatomical institutes has compiled its own preservation method for embalming, which involves the inserting of a cocktail of chemicals, often containing the chemical compound formaldehyde. Embalmed bodies are mostly used for anatomy basis education of students. A relatively new technique in the Netherlands is the freezing of bodies. Defrosted bodies approximate real living bodies better than embalmed bodies and, therefore, are often used for the training of post-academic skills of for example surgeons. However, the institute in Groningen has started to use the Thiel-embalming method (Thiel, 1992). These embalmed bodies retain life-like flexibility and colouring and are therefore also very suitable for post-academic education of several (surgical) procedures.

Some institutes have started to use the technique of plastination for the preservation of body parts. Plastination is a preservation method invented by Gunther von Hagens in 1977 in Heidelberg, Germany. The method consists of replacing the natural body fluids with a plastic to preserve the tissue. In contrast to embalmed bodies which are wet, plastinated bodies are dry and odorless, which makes them suitable for exhibitions. The first exhibition with plastinated bodies was *Body Worlds* from Von Hagens in Japan in 1995 and has been travelling through the world ever since (Bolt, 2009). The millions of visitors and the major media attention for the exhibitions have made plastination a well known preservation method among the general Dutch population. Consequently, there are also Dutch people who wish to bequeath their body to Von Hagens. The institute in Groningen even had experience with people who deregistered because they changed their mind and preferred to donate their body to Von Hagens. In the Dutch anatomical institutes plastination is only applied to body parts. Since the technique involves the handling of chemical agents which are normally not used by anatomical professionals, only the institutes who have made serious investments to guarantee safety can employ plastination (Holladay et al., 2001).

The Dutch anatomist are organised in the NAV (*Nederlandse Anatomen Vereniging*), an anatomical society founded in 1930 of people employed by one of the eight Dutch anatomi-

cal institutes or the two anatomical institutes located in Flanders, the Dutch-speaking part of Belgium. The NAV organises an annual scientific meeting with the goal of promoting the exchange of information pertaining to all aspects of anatomical science (Bolt et al., 2011b). Since there is no national coordinating organization involved in Dutch body donation, within the NAV, there are plans to build a national website where people can find useful information about, for example, body donation, temporary registrations stops, and contact details and procedures of the various anatomical institutes.

Increased registration numbers

Over the past several years, Dutch body donor registrations have been increasing. The institute in Groningen (UMCG) also found that a substantial number (on average 29%) of the persons registered between 2003 and 2008 died within 1 year after registration and seemed to have made a 'last-minute' donation decision (Wijbenga et al., 2010). To avoid a surplus of incoming bodies, several anatomical institutes have actually decided to decline new registrations (Bolt et al., 2010). Currently, there are about 16,000 registered body donors in the Netherlands (0.1% of the total population). Each year, about 650 whole bodies are donated to the institutes, which is sufficient to meet the anatomical demand (Bolt et al., 2011b).

A recent body donor survey (n = 759) was conducted to study motivation for body donations. The study shows that the majority of motives (93%) stem from the wish to be useful after death. Donors want their death to be meaningful. They strive to contribute to science and education and they feel that despite their death, they can still help others. About half (49%) of the donors considered body donation as a way to express gratitude for medical science and health care. And only a few donors (15%) seemed to be motivated by a negative attitude towards funeral rites and practices (Bolt et al., 2010).

Commemoration

Most relatives of body donors remain unaware of what will happen to the corpse of a body donor, let alone the time of its final disposal. Because of practical and logistical reasons this is often not possible, because the body can be cut up in different parts that will

not be disposed of at one and the same time. Some body parts happen to be used by the anatomy institute for many years, such as the ones preserved with the technique of plastination. The anatomical institute in Maastricht is the only institute that offers bereaved the possibility of being present at the final cremation of the remains (Bolt and Venbrux, 2010). In 2007, the first monument for body donors was unveiled at the anatomical institute in Groningen (UMCG). This ceremony was the first time a Dutch anatomical institute paid public commemorative attention to body donation. In 2009, at the institute in Nijmegen (RUNMC) (Kooloos et al., 2010) another monument for body donors was unveiled and in 2011 in Utrecht (UMCU) as well. Anatomical institutes in Amsterdam, Rotterdam, and Maastricht also declared that they were interested in building a monument. The anatomical institutes increasingly acknowledge that body donors represent real human beings with relatives that mourn. This change in attitude has resulted in the wish of anatomical professionals to reciprocate body donation, not only for the donors but in particular for their relatives. The relatives respect and fulfil the donor's wish and hand over the corpse to an anatomical institute. Thereby doing so they give away the possibility of organizing a funeral in the presence of the corpse and accordingly have no grave or urn to visit. The monuments are significant to many bereaved because they create a symbolic final resting place filling the vacuum caused by the bodily absence of the donors (Bolt, 2011).

PERSPECTIVE FROM PORTUGAL (PROFESSOR D. PAIS)

The original contribution, published in 2008 by the authors is still valid, because there have been no changes in Legislation pertaining to body bequest in Portugal since then. We should mention that there is very recent news of an intention of the Medico-Legal Council of Portugal (National Institute of Forensic Medicine of Portugal) to revise the law on body bequest for teaching and research purposes, which dates from 1999.

Recently, in the two larger cities in Portugal public exhibits with dissected human bodies received a total of 200.000 visitors. The cadav-

ers in the exhibit were not from Portuguese donors. Controversial as these exhibits always are, we must say that they received a majority of favorable opinions from the general public. It was stated by the organizers that all the bodies are from people that had freely bequeathed their bodies to science and education. Without wishing to enter the controversial discussion on whether it is morally or ethically acceptable to display real dissected human bodies in public, with or without commercial profit, we wish to point out that the bequest of human bodies for teaching and research does not legitimize their public exhibition. In Portugal, informed consent for this specific purpose would have to be mandatory, the reason for this being that the Portuguese law mentions “bequest for teaching and research” and not “bequest for science and education”. Therefore, bequeathing the body for teaching and research does not include public exhibition of the whole or parts of the body.

Traditionally, bodies bequeathed in Portugal were mainly used for scientific research projects and for pre-graduate teaching of medical and health sciences students. Lately, Medical Schools have been receiving more and more demands for post-graduate teaching and training for residents and specialists of a large variety of medical and surgical specialties using human cadavers. In our view, these are educationally commendable initiatives and they may be considered ethically acceptable as long as the financial counterpart received by Medical Schools only aims at supporting extra staff and maintenance expenses. Organizing courses or workshops that use donor bodies or body parts to make profit would not be ethically or legally acceptable.

PERSPECTIVE FROM ROMANIA (PROFESSOR A.R.M. CHIRCULESCU)

There is nothing new about regarding recent Romanian regulations on body donation. The previous statements remain as published in 2008 remain 100% valid.

PERSPECTIVE FROM SPAIN (PROFESSOR J.L. BUENO-LOPEZ)

The original contribution of Spain is still valid; no changes have been introduced into the law. However, the Spanish Anatomical

Society is concerned about the possible occurrence of other societies or companies that try to lure naïve, non-paid donors through calls for charitable contributions to science. However, such contributions may supply bodies for a price and destined for expensive post-graduate courses and for the training of medical specialists. Perhaps it is important to note that the departments of anatomy in Spain do not reward donors monetarily, although they do pay their funeral expenses.

PERSPECTIVE FROM SWITZERLAND (PRIVATDOCENT DOCTOR B.M. RIEDERER)

Here, I will summarize two recent publications that address body donation and research with human subjects and that apply to Switzerland. Both underline the basic principles of consented and informed body donations. The first publication is „**On the use of cadavers and parts of cadavers in medical research and for pre-, postgrad and continued education**“ (SAMS, 2008). The second one is a detailed manual, entitled „**Research with human subjects**“ (SAMS, 2010). Both documents are recommendations that come from the *Swiss Academy of Medical Sciences* (SAMS). Here, I will extract the essentials of the two publications and also add some comments.

The first publication (SAMS 2008), edited in German and French, is specific on the use of cadavers for medical education at various levels, pre- postgraduate or continued education, and was published at the same time as the TEPARG work in 2008. In the introduction it was mentioned how it came to this publication: they were quite critical about the “current” situation that body parts can be imported from all over the world into Switzerland and can be used for medical training. In 2006, two newspapers reported the importation from the US to Switzerland of 40 fresh feet for surgical training. This event showed that there are missing guidelines and consequently resulted in the constitution of a working group to establish recommendations on the use of cadavers and body parts for medical training and research in Switzerland.

By Swiss laws, the use of human bodies is defined in different ways, but still leaves open some space for reflection and interpretation.

Nevertheless, some basic principles apply, in that the human body or body parts do not serve to make profit, while costs deriving from the preservation and treatment of human bodies are excluded from this principle. In general, any commerce with human bodies and body parts is forbidden. Body parts cannot be removed without prior consent of the donor and can only be used as stipulated in the consent form. In addition, the Federal constitution of Switzerland adds that human dignity needs to be preserved. The penal code also protects human cadavers from any unauthorised intervention.

The paper puts forward several recommendations as how to improve body „commerce“. An important point seems to be informed consent, which applies to modern standards of biomedical ethics and allows the integrity of a given person to be preserved. Such consent is given while the donor is still living. This is standard practice in human body donation. Nevertheless, if a potential donor has not announced his/her will, the family can still declare that the deceased relative is willing to participate in a donation program. However, this is not accepted everywhere. Prior to any use, a project needs to be defined and approved by the local ethical committee. This practice varies between countries and cultures.

A delicate issue is the publication of human data and results on anatomical research. How far are the different local directives on the use of human bodies comparable? Journals need international guidelines on ethical conduct when it comes to publishing results. So far, the Helsinki declaration is widely accepted and principle 30 is cited as reference for guidelines by several Journals (Helsinki declaration, 2008).

Consent for biological research: this is part of the formulation in most treaties between a donor and a given institution. This also reflects the trust between donors and the receiving institution. Yet there are points that need to be discussed in relation to “relative consent”. It is widely accepted that Anatomy and Pathology Institutes or Legal Medicine use cadavers for teaching and research, and this does not imply that projects have not been specified, therefore relative consent. This practice is widely accepted. Recommendations for collecting tissue samples were published in 2006 (5). In addition, we are given regarding

the conservation and use of biological material of human origin. Also here, informed consent and data protection prevail, and in addition those responsible for the management of a biobank must ensure that human biological material is transferred to third parties only in anonymized form.

Human cadavers are widely used for teaching in recognized institutions. What happens when courses are organized by externals (non-members of anatomical institutes or hospitals), or when bodies and body parts are exchanged between anatomical institutes? The responsibility still remains with the institution that made contract with the donor, and is therefore also responsible for the cremation of those bodies and body parts. Such a practice is also covered by relative consent. In the future, critical surgical steps may require further investigations and validations and the use of body parts may even increase, whether according to specified ethical standards or not. In Switzerland, all anatomical institutes have comparable declaration forms that specify the use of donated bodies in relation to medical education and research. Furthermore, additional information can be given to future donors or relatives and the staff is available to answer any question and are open to discussions. In addition, the Swiss anatomical institutes have a regular exchange of information in teaching programs, as well as interaction with third parties (i.e. with physicians from hospitals or with industry).

The second publication to discuss is the manual for general practice (SAMS, 2010), which covers all aspects to do with with human research subjects (in 13 chapters, on 82 pages) and goes in depth into all possibilities in research and applications. Therefore, only those parts that may apply to body bequests and the use of donations will be discussed here. This manual was published in English and interested readers can find further details in the original publication. In addition, this document contains several appendices, including a helpful glossary for terms and the Helsinki Declaration (World Medical Association, 2008), summarizing the Ethical principles for Medical Research Involving Human Subjects, and comprises 35 points, previously 37 (Helsinki declaration, 2008).

1) *History*. History of research with human subjects began in the 18th century and this

part details the ethical dilemma between tests on human subjects and benefits for the patient.

2) *Terminology and areas of activity.* This includes a discussion on research with human subjects concerning any manipulation with human subjects and concerns all aspects, medical nursing, pedagogic, psychological, economical etc. Pharmacological studies are instead related to clinical trials. Epidemiological studies are aimed at investigating health and disease in different populations, Sociological and humanistic research concerns psychology, nursing science and the underlying behavioural relationships and social interactions.

3) *Legal conditions.* Legal conditions, general principles and rules that are applicable in Switzerland for research with human subjects are discussed and compared at international, Federal and cantonal levels. The Federal law regulates various medical aspects, including drugs or stem cell use. There is a broad consensus that a researcher should not carry out a study against the wishes of the participant. In respect of cantonal laws on health and hospitals, the guidelines make reference to the Helsinki Declaration and there is much consensus between the various cantonal regulations.

4) *Principles of research ethics.* These are – in respect of persons, maximisation of benefits, justice,- and applies to cadavers, where respect of the person prevails. Several paragraphs deal with the conception and performance of studies. This can also be indirectly applied to studies on cadavers, and hence tus ethical and quality standards on donated bodies and the acquisition of valuable information should be maintained. This also includes a reflexion on research ethics, appraisal by a research ethics committee, free, informed consent of the study « participants », applying also to body donors, a continuous critical assessment of the procedures, and the rules of research technology.

5) *Science.* The scientific character must meet all the requirements of scientific methodology and lead to valid and reliable results; otherwise such research is not justified. It includes avoidance of bias – create control groups, randomisation and binding, repetition of studies, concise, formalized inclusion and exclusion criteria, as applies for any study. Adequate statistical procedures are of great importance. The definition of quality criteria

is essential, with a description of the exact protocol of the steps to be implemented. Such a description of the applied method is essential for scientific conduct, evaluation of the study but also essential to stated specifically needs to be transmitted to body donors and their families, to maintain transparency of the procedures applied (this includes information on the long-term preservation of body parts, such as for plastination, used for medical teaching – but how far should we go in the description of the procedures – dissection, etc.?).

6) *Informed consent.* In research ethics this is a basic precondition for research with humans. Information about the study participants is essential. Although not written specifically, this also applies for organ and body donation. Donors (or as described in the document, study participants) must document their voluntary consent to take part in the study – or donate their body to science with their signature. However, some exceptions may apply where the consent of study participants is not possible and consent by Proxy is needed (children, persons in a coma, mental illness etc.).

The information for study participants should contain the following elements (only those that also apply to body donations, and for the use of bodies in teaching and research are mentioned here):

- general description of study
- reasons for selection
- indication of the voluntary nature of the participation
- study design and study procedure
- other possible therapeutic methods
- agreement on confidentiality and data protection
- reimbursement and details of compensation
- address and telephone No. of a contact person

It also seems helpful to have an address for questions and supplementary information, as well as description of the procedure to be followed after the death of the donor. The signature of an agreement to participate has two effects: For one, the person authorises the researchers to carry out the various procedures; and secondly the signature is also a legal consent, valid in accordance with the legal and institutionally defined rules. Regarding *voluntary consent*, this can only given by a person who is capable of judgement with regard to

this decision and whose judgment is independent. Informed consent is only possible when all relevant information has been made available and has been understood. By signing, the consenting person is expressing his/her wish to participate. However, in practice there may be some limitations in that that capability may be limited by illness, or the study information that is given may be not sufficient, or the person perhaps does not understand all the details of the documentation given.

Consent by Proxy: A problem may arise in a situation where the person him/herself is not in the position to give consent (children, patients in a coma, or the mentally ill). In such a situation, another person who is authorized by law (representative) must consent or decline. In view of body donation for scientific purposes, this is by no means clear for sick persons where the family decides to donate the body of their diseased relative to science. It is preferable to have to consent for a body donation while the donor is still living. Limitations of informed consent, from an ethical point of view, it is important in what way the information is communicated and needs some sensitivity for contact persons.

7) *Considerations of opportunities and risk and assessment of acceptability.* This is of lesser importance for body donations, since “harm to be expected” does not apply to cadavers. However, it is rather the opposite: that personnel that have to deal with diseased persons need some protection from certain bacteria and also need vaccinations to prevent the propagation of contagious diseases.

8) *Ethical problems with individual study designs.* This question applies more for randomised studies where the participants need to be placed in different groups. This may, however, apply to post-mortem studies with specific tissue samples. Randomisation, and/or blinding may partially apply, but are of lesser importance for the donor, while placebo is not applicable. The 4th paragraph is much more relevant, since it deals with the collection, storage and use of human samples for the purpose of research, and concerns « biobanks » with some guidelines (SAMS publication, 2006). Art.22, Convention on Biomedicine and principle 25 of Helsinki Declaration states: If in the course of an intervention a part of the human body is removed, it may be

stored and used only for the purpose for which it was removed; for any other use, appropriate information and consent procedures must be followed. However, in the case of body donations, this may necessitate proxy consent and considerations and approval by a research ethics committee. The data from the patients' case history need to be protected.

9) *Ethical assessment of studies involving humanistic and sociological questions.* Life history is seemingly a difficult part to reveal, and it is always difficult to obtain the necessary information, except for donations that have been planned and/or accompanied for a long time. This mostly concerns the divulgence of personal information. Yet for teaching human anatomy the life history of donors is not relevant and not revealed to the students. For research, such information may be, in parts, of importance, and made available only when donors had given prior consent.

10) *Protection of groups or individuals.* This goes with protection of data and is at the centre of any study. No names or personal data of the participants should be mentioned in any medically applied research. When it comes to cadavers in a dissection course, it is essential to prevent that any student enrolled in such studies from coming into contact with a relative that donated his or her body, and the students from knowing the names of people (cadavers) that are dissected during the teaching program. Children and adolescent under the age of 18 years are not enrolled in donation programs, nor are pregnant women acceptable. Formulated also in the Helsinki Declaration, principle 17.

However, emergency situations may prompt some aspiration towards donation programs. Given the different procedures to get into donation programs may very often cut short on expectations. It is essential to have different committees able to supervise such matters such as ethical committees for medical research, which may allow the definition of clear directives for medical research.

Persons in prison or in detention, in developing or low-income countries, or vulnerable persons may need protection from an overly active prospection of body or organ donations, mostly for economic reasons. Therefore, to prevent temptation regarding commercial influences commerce with human organs should be banned. While research with

human subjects is often cost-intensive, conflicts of interests or other unfavourable influences may influence a decision. Thus, a strict definition and follow-up of studies is advised. This also means a clear definition of any contribution to a researcher or research projects.

12) *Trust, confidentiality and data protection.* It is important to maintain data protection for any individual enrolled in study programs (including body donors). Trust is the base of any study program or body donation. Therefore, it is essential to protect personal data. Data protection is imposed by law. Despite the fact that the personal case histories represent a valuable source of information for clinical or epidemiological research, they may be used only if conditions are clearly defined. For publications and lectures it is also essential to anonymize images.

13) *Review by a research ethics committee.* It is standard international practice to submit research projects with human subjects to a research ethics committee, (similar to animal research), as based on the Helsinki Declaration of 1975, principle 15. In many countries, any work on humans (or animals) must have approval by an ethics commission. The verdict is essential to approve proposed protocols or procedures. However, in Switzerland the approval of most scientific proposals is judged by the Swiss Science Foundation, while the ethical aspects are approved by local ethical commissions. Although a project may have scientific merit, without approval from the ethical commission no money can be given out for the specific research project. It is therefore of utmost importance to establish tasks and responsibilities in a project, the working method, define the elements or milestones of a study, the structural conditions and regular evaluations of a study, and describe the limits or dangers of a proposed study.

In conclusion, much is regulated in Switzerland. However, there is still room for interpretation. These strict regulations are not only to protect donors but also concern the receiving institutions, and provide legal framework for the use of human bodies for research and teaching. They are also designed to guarantee the optimal use of cadavers and to prevent any misconduct or abuse of human bodies and body parts in teaching and research.

PERSPECTIVE FROM TURKEY (PROFESSOR E. SENDEMIR)

Turkey, with its 73 million inhabitants today, has 74 medical and 30 dental schools (2011), recruiting more than 5000 students per year to these schools. This means Turkish schools should optimally be dissecting about 500 cadavers per year. Unfortunately, this is not the case. Although there is an increased need for cadavers, we are facing a sharp decrease in supply.

For many years, the major source of cadavers has been the unclaimed bodies from mental and state hospitals. The rehabilitation of mental hospitals in late 1980's caused a dramatic decrease in cadaver supply. Since funeral services are almost free, this cannot be a reason for leaving one's body to anatomy institutes. And the reaction of people regarding the use of unclaimed bodies as cadavers is negative for many reasons. Currently, Turkish medical and dental schools are facing a real shortage of cadavers. There are schools which have not dissected a cadaver over the last 8-10 years; some schools have been using prosected materials for many years.

This situation is a result of cultural background rather than any religious restriction. Although there are no statements against dissection in either the Koran or in the Tradition of the Prophet, the first officially permitted dissection of human cadavers in the Ottoman Empire was made in 1841 (Kahya, 1979; Erimo lu, 1998).

The Turkish Religious Affairs Supreme Council made a positive comment on autopsy in 1952 and heart transplantation in 1968. In 1980, the same Council declared that organ transplantation was appropriate to Islam upon the debates on organ transplantation in the public at large.

Public attitudes toward cadaver donation have not been analyzed in Turkey but the campaigns to increase cadaver organ donation have not been successful enough to reach sufficient transplantation numbers. Considering donations as cadavers, although self-donations are seemingly becoming higher, the real number of the dissections done on donated bodies is less than the number of one hand's digits (Sehirli et al., 2004). In their study, Sehirli and colleagues observed that 63.9% of the Turkish anatomists would not consider donating their bodies.

“Finding” the cadaver, transportation, fixation, and keeping the records is almost the same as the Romanian perspective (Haberler, 2005). The district attorney is responsible for the “fate” of the unclaimed bodies and his/her permission is required. There are no cremation units anywhere in Turkey, so when the time comes cadavers are buried by the department of the municipalities responsible and their burial sites are reported to the DA.

Students are informed about the origins of the cadavers that they are going to study and are encouraged to show respect to the deceased, who are evidently not there by their own will. Photographing or video imaging is not allowed in any dissection room. Because of flagging numbers, only residents have been dissecting over the last 10-15 years, while students have only been allotted prosected material.

If a person is willing to donate him/herself as a cadaver he/she usually refers to the head doctor of the university hospital since this issue is not much publicized. Then, the person in question is asked to go to the Anatomy Departments. There, every question is answered, and their written bequest is taken in which they can state the place they wish to be buried, if any religious service is desired, etc.

The Turkish Society of Anatomy and Clinical Anatomy is involved in the search of a solution for the unclaimed bodies so that they would “have to be” referred to the medical schools instead of their contemporary “may be” referral. In this regard many attempts have been done by the Ministry of Health as well as the Ministry of Justice and even with the Supreme Court of Religious Affairs. The Turkish Society of Anatomy and Clinical Anatomy believes that education in anatomy must include cadaver dissection and today’s situation is could somehow lead to severe defects in the education of medical/dental students and, also, residents. Our Society anticipates that until the problem is solved, there could be cadaver transfers under the surveillance of the IFAA between countries who might have surplus cadavers.

The law and regulations concerning cadavers is mostly centered to the *Harvesting, Storage, Grafting and the Transplantation of Organs and Tissues* article, which clearly states the willingness of the deceased or the relatives unless the deceased person has stated the opposite (Regulations, 1979).

The most important part concerning cadavers is Addendum-2 of Article 14: the “Regulation Concerning Scientific Research on Human Cadavers” as “those who make testaments for their bodies to be donated to scientific research, and those who die while in a medical facility and are brought to the morgues of such institutions, can be used for scientific research at Higher Education Institutions if claim is not made by family or next of kin within six (6) months of the date of death, provided that the person was not in any way a subject of judicial prosecution, unless otherwise stated in their will”.

The above law was amended by Law numbered 2594 and dated 21/1/1982 and some descriptions were supplemented to the above paragraph concerning the scope and definitions for the “Cadaver for whom no claim is made”, “Testamentary cadaver”, “Stations for Embalming and Storage of Cadavers”, “Respect for the dead body” which are also mentioned in a later law (Turkish Civil Code, 2001). According to these regulations Higher Education Institutions - namely Departments of Anatomy at Faculties of Medicine- are responsible for taking measures for storage, usage, keeping records and appropriate burial of the cadavers either unclaimed or testamentary.

PERSPECTIVE FROM THE UNITED KINGDOM (PROFESSORS B.J. MOXHAM , S. MCHANWELL AND D.C. DAVIES)

The bequest of bodies for anatomical education and research has been governed by laws contained in a series of Acts of Parliament, the Anatomy Acts of 1832, 1871 and, more recently, 1984. The early history and the reasons for the introduction of the Anatomy Acts of 1832 and 1871 have been described in detail by Ruth Richardson (2001) and so will not be repeated here in detail. The 1832 Act was ostensibly introduced in response to the public outcry following the prosecution and conviction of Burke and Hare and the subsequent execution of Burke in Edinburgh (Hare was reprieved in return for his co-operation in solving the case). However, Richardson (2001) argues persuasively that an effect of the Act, through permitting unclaimed bodies of paupers dying in workhouses to be claimed by anatomy departments, was to make those

workhouses places to be feared. The willingness of some departments to claim pauper's bodies rather too quickly, before relatives had been given adequate time to claim them, resulted in a series of public scandals. Nevertheless, it was another thirty nine years before the Act of 1832 was replaced by the Anatomy Act of 1871, a principal provision of which was to require consent to be given before a body could be used for anatomical examination. Thus, the intention of the Act of 1871, in allowing donation by consent, was very much in keeping with the public spirit of the times. This Act served its purpose well for over one hundred years, with just some minor amendments being added in the Anatomy Act of 1984. The introduction of the Human Tissue Act 2004 subsumed the regulation of anatomical bequests. The Human Tissue Act 2004 built upon earlier legislation. Consequently, in order to understand the provisions of the Human Tissue Act and how it differs from previous legislation, it is necessary to understand what preceded it. The Anatomy Acts of 1871 and 1984 regulated two major aspects of practice in relation to the bequest of cadavers for anatomical examination. The Acts licensed premises in which the bodies were to be stored, maintained and examined, and they also licensed individuals (Licensed Teachers) who were responsible for ensuring that the provisions of the Anatomy Acts were complied with. Compliance with the Act was enforced by His / Her Majesty's Inspector of Anatomy, with jurisdiction throughout the United Kingdom to ensure equal compliance with the Anatomy Act and to disseminate good practice. The duties of the Inspector of Anatomy were several:

- He / She made the recommendation to approve the licensing of premises for anatomical examination and the licensing of teachers themselves.
- He / She maintained records of licensed premises and teachers and of the bodies accepted for anatomical examination, where they were held and when they were disposed of.
- He / She visited premises biannually to ensure they were secure, appropriate for purpose and properly maintained.
- He / She also ensured that that appropriate consent was in place, parts were retained in accordance with the law,

records were kept and that the cadavers and parts were maintained in an appropriate state.

Premises licensed for the storage of human bequests had to be secure and suitable for maintenance of bodies in a condition suitable for examination. Access to the premises had to be restricted to teachers and *bona fide* students of anatomy. Human material was not permitted to leave licensed premises without official approval, it could only be used for anatomical examination and not surgical practice and photography that permitted identification of the donor was prohibited.

Both the premises and those working within them were under the direction of a Licensed Teacher (or Teachers) of Anatomy. Licensed Teachers had to be of 'good standing' and their appointments had to be approved by a magistrate. Licensed Teachers had many responsibilities under the Anatomy Acts. They were responsible for ensuring that legal consent for a bequest had been obtained. Once the body was received, Licensed Teachers were required to inform the Inspector of Anatomy of the receipt of the body. Licensed Teachers had to ensure that proper records or all donations were kept locally and also supplied to the UK Government's Department of Health. Licensed Teachers had also to make the licensed premises available for biannual inspection by H. M. Inspector of Anatomy.

Arrangements for communicating with potential donors, registering donations and accepting the body after death varied in detail between different departments of anatomy, but the same general approach was adopted throughout the UK. At Cardiff, the response to an initial enquiry was to send out a note explaining the process to donors, describing the uses to which the body would be put, and the length of time the body could legally be retained. Donors were informed that the department did not guarantee to accept bequests. Donors were also asked to discuss their wishes with their next of kin and place a written statement of intent with their papers (e.g. legal will and testament). They were also asked to complete a form and return it to the department signifying their intentions. Donors were advised that costs of transport to the department upon decease would only be paid if the place of death was less than 50 miles from Cardiff and that the School would

meet the costs of disposal. After notification of a donor's death, the department sought information about the medical history from the doctor who registered the death and a decision taken about whether or not to accept the body. Refusal to accept a body could be based upon health and safety considerations (e.g. history of dementia or certain other neurological pathologies, infections such as MRSA, and hepatitis) or because the history of disease rendered the use of the body impractical (e.g. autopsy, transplantations, cachexia, major surgical interventions) or because the body was not suitable for use in the dissecting room (e.g. over- or under-weight bodies; numbers surplus to requirements). If a decision was made to accept a donation then the undertakers were informed and given a form that the relatives had to complete confirming the intentions of the deceased and signing a statement about whether or not the deceased would have wished any parts to be retained. Once the Medical Certificate of the Cause of Death had also been received, the body could be accepted. At this point, the Inspector of Anatomy was also notified. At the end of the period during which the body was retained, the department made arrangements for disposal by cremation (or sometimes burial). The relatives were informed. Parts of the body could only be retained beyond this time by express consent of the donor or their relatives. Relatives were invited to the committal service, although in practice few chose to attend. However, as for most other departments in the United Kingdom, an annual "memorial service of thanksgiving" was conducted during the year of donation to thank the donors for the gift of their bodies for teaching and research. Relatives of the donors, staff and students were invited to attend this event.

Although the Anatomy Act had been in force, and had worked well, for over 100 years, in 2004 a new Act was passed in the UK called the Human Tissue Act. The introduction of this Act was prompted by a series of issues relating to the acquisition and retention of pathology specimens and, while anatomy departments had continued to operate well under existing legislation, it was felt by Government that a single unifying legislative framework was required to control all use of human tissue. This view was opposed by many anatomists who would have preferred to

retain separate regulation under an Anatomy Act. The operation of the Human Tissue Act is currently regulated by the Human Tissue Authority that has drafted a Code of Practice to control anatomical examination. There are important differences between the Human Tissue Act and the previous Anatomy Act:

1. The Human Tissue Act covers all donations of human tissues (including material for transplantation and pathology and tissues banks). Anatomical examination is therefore a relatively small part of its remit, which is low risk because of its long history of regulation.

2. Under the Human Tissue Act there is no longer a specific individual with responsibility for anatomical examination -cf HM Inspector of Anatomy- but a Regulation department within the Human Tissue Authority that covers all aspects of the use of human tissue covered by the Act, (e.g. inspection of tissue banks and pathological collections etc).

3. Consent is the cardinal principle underlying the Human Tissue Act. This consent must be informed consent (so detailed information for potential donors must now be provided to enable them to come to their decisions) and for anatomical examination must be given in writing by the donors in their lifetime and witnessed.

4. Each 'scheduled purpose' under the Human Tissue Act has its own Code of Practice and there is one specifically for anatomical examination, storage, and disposal. Overall, there has been a major increase in paperwork and bureaucracy compared to regulation under the previous Anatomy Act, although there are no longer online forms to be completed.

5. Standard operating procedures (SOPs) are now required for all activities relating to anatomy.

6. Export and import of anatomical material are possible within defined parameters.

7. Public display of anatomical material is possible with appropriate consent, but requires special licensing.

8. Images of the material in the dissecting room can only be taken with consent of the donor before death. Note that it is the use to which the images are put that may make their use illegal.

9. It is now possible, with the appropriate consent, to extend the use of cadavers from

simple anatomical examination to the use of material for research and for clinical training.

10. Anatomical specimens may (with appropriate consent) be kept beyond the 3 year limitation previously set as the norm under the Anatomy Act.

11. The Licensed Teacher of Anatomy in the Anatomy Act has been replaced by a Designated Individual who need not necessarily be an anatomist.

12. Although not a legal requirement, committees (such as a Governance Committee) may be set up within anatomy departments to help regulate and manage the activities associated with anatomy.

CONCLUSION

Previously, we have reported on body donation and frameworks in place in several European countries (McHannwell et al., 2008). Given the complex and various legislations in place, we felt that it was time for an update. Here we have provided additional information on the latest developments in legal and ethical applications and have integrated novel contributions from Malta, The Netherlands and Turkey. At the same time, we hope that this summary will help to lead to commonly applicable directives on body donation and practical applications for anatomical institutions. It is by far evident to harmonize that a variety of legal, religious and ethical frameworks need to be considered and integrated. One point that transpires from several contributions is the lack of control in the import/export of bodies and the need to have a tighter regulation. A second point is the commercialization of human body parts. This should be prohibited. Selling body parts for profit is already prohibited in several legislations. In our opinion, the act of donating a body should be voluntary and should not be used for generating money. This is also to reinforce the trust in donation, since donations are essential for the progression of the medical sciences and medical education. In addition, ethical considerations mean that we must respect the act of donation. Therefore, there is a need to establish a common regulation on the use of human bodies, both in Europa and worldwide.

REFERENCES

- AVIS DU CCNE (2010) Le Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé: sur les problèmes éthiques posés par l'utilisation des cadavres à des fins d'exposition. Avis 111 publié le 20/09/2010.
- BOLT S (2009) Body disposition. In: Bryant CDB, Peck DL, editors. *Encyclopedia of death and the human experience*. Sage, Los Angeles, pp 107-111.
- BOLT S (2011) Dead bodies matters. The gift of body donor monuments in the Netherlands. Submitted to *Medical Anthropology Quarterly*.
- BOLT S, VENBRUX E (2010) Funerals without a corpse: awkwardness in mortuary rituals for body donors. In: Michaels A, et al., editors. *Ritual Dynamics and the Science of Ritual. Body, Performance, and Experience*. Harrassowitz, Wiesbaden, pp 221-233.
- BOLT S, VENBRUX E, EISINGA R, KUKS JBM, VEENING J, GERRITS PO (2010) Motivation for body donation to science: more than an altruistic act. *Ann Anat*, 192: 70-74.
- BOLT S, EISINGA R, VENBRUX E, KUKS JBM, GERRITS PO (2011a) Personality and motivation for body donation. *Ann Anat*, 193: 112-117.
- BOLT S, VENBRUX E, EISINGA R, GERRITS PO (2011b) Anatomist on the dissecting table? Dutch anatomical professionals' views on body donation. *Clin Anat*, DOI: 10.1002/ca.21215.
- COURT DE CASSATION (2010) Arrêt de la Cour de cassation, Chambre civile, rendu le 16/09/2010, rejet, pourvoi n°09-67456.
- DE CARO R, MACCHI V, PORZIONATO A (2009) Promotion of body donation and use of cadavers in anatomical education at the University of Padova. *Anat Sci Educ*, 2: 91-92.
- EUROPEAN PARLIAMENT COUNCIL COMMISSION (2007) Charter of Fundamental Rights of the European Union. In: European Union (Hrsg.) 2007/C 303/01: European Union 2007.
- ERIMOGLU C (1998) Anatomi. In: Unat EK, ed. [Dünyada ve Türkiye'de 1850 yılından sonra tıp dallarındaki ilerlemelerin tarihi.] stanbul: Cerrahpa a Tıp Fakültesi Vakfı Yayınları; 1998. p. 26-31.
- HABERLER (2005) http://www.trakya.edu.tr/Haberler/bagis_kadavra.htm
- HANSEN JV (1996) Resurrecting death: anatomical art in the cabinet of dr. Frederik Ruysch. *The Art Bulletin*, 78: 663-679.
- HOLLADAY SD, BLAYLOCK BL, SMITH BJ (2001) Risk factors associated with plastination: I. Chemical toxicity considerations. *J Int Soc Plast*, 16: 9-13.
- HUISMAN T (2008) The finger of God. Anatomical practice in 17th-century Leiden. In: Leiden: Universiteit Leiden.
- Human tissue act (2004) <http://www.legislation.gov.uk/ukpga/2004/30/contents>.
- KAHYA E (1979) [Bizde disseksiyon ne zaman ve nasıl ba ladı?] When and how the dissections begin by us? *Bellelen* 172: 739-759. [in Turkish].
- IJPM FFA, VAN DE GRAAF RC, PIERIK EGJM, VAN GULIK TM (2009) De meesterproef in de chirurgijnsopleiding. *Nederlands Tijdschrift voor Geneeskunde*, 153: 1-7.
- KOOLOS JGM, BOLT S, VAN DER STRAATEN J, RUITER DJ (2010) An altar in honor of the anatomical gift. *Anat Sci Edu*, 3: 323-325.
- MACCHI V, PORZIONATO A, STECCO C, TIENGO, PARENTI A, CESTRONE A, DE CARO R (2011) Body parts removed during surgery: a useful training source. *Anat Sci Educ*, 4: 151-156.
- MAYER E (2010) Der Umgang mit der Leiche. Thesis: Institut für Strafrecht und Kriminologie. Wien: Universität Wien 218.

- MCHANWELL S, BRENNER E, CHIRULESCU ARM, DRUKKER J, VAN MAMEREN H, MAZZOTTI G, PAIS D, PAULSEN F, PLAISANT O, CAILLAUD M, LAFORET E, RIEDERER BM, SANUDO JR, BUENO-LOPEZ JL, DOÑATE F, SPRUMONT P, TEOFILOVSKI-PARAPID G, MOXHAM BJ (2008) The legal and ethical framework governing Body Donation in Europe - A review of current practice and recommendations for good practice. *Eur J Anat*, 12: 1-24.
- REGULATIONS (1979) Regulations Concerning the Harvesting of Organs and Tissues from Cadavers and their Storage for Scientific Research. 29.5.1979. <http://www.saglik.gov.tr/TR/belge/1-445/tarihi29051979—sayisi2238—rg-tarihi03061979—rg-sayis-.html>.
- RICHARDSON R (2001) Death, dissection and the destitute. 2nd edition, ISBN 9780226712390. University of Chicago Press.
- RIJKSOVERHEID (2010) Wet op de lijkbezorging. Retrieved April 29, 2011, from http://wetten.overheid.nl/BWBR0005009/geldigheidsdatum_22-06-2010.
- SAMS (2008) Swiss Academy of Medical Sciences: Verwendung von Leichen und Leichteilen in der medizinischen Forschung sowie Aus-, Weiter- und Fortbildung. Published 27 november 2008. <http://www.samw.ch/de/Ethik/Richtlinien/Aktuell-gueltige-Richtlinien.html>.
- SAMS (2010) Swiss Academy of Medical Sciences: Research with Human Subjects; A manual for general practice. Published 1.4.2010. <http://www.samw.ch/en/News/News.html>.
- SAMS (2006) Swiss Academy of Medical Sciences: Biobanks: Obtainment, preservation and utilisation of human biological material. published May 23, 2006. <http://www.samw.ch/en/Ethics/Guidelines/Currently-valid-guidelines.html>.
- SEHIRLI US, SAKA E, SARIKAYA O (2004) Attitudes of Turkish anatomists toward cadaver donation. *Clin Anat*, 17: 677-681.
- Staatsblad van het Koninkrijk der Nederlanden. jaargang 1869. no 65.
- THIEL W (1992) Die Konservierung ganzer Leichen in natürlichen Farben. *Ann Anat*, 174: 185-195.
- TURKISH CIVIL CODE (2001) 22.11.2001. <http://www.mevzuat.adalet.gov.tr/medeni/medeni.htm>.
- VAN DER HAAR J (1964) Lijkbezorgingsrecht. In: Amsterdam: Vrije Universiteit Amsterdam.
- VAN DER PUTTEN WGHM (1992) Wet op de Lijkbezorging. Zwolle: W.E.J. Tjeenk Willink.
- VAN KINSCHOT HF (1969) Wet op de lijkbezorging. Zwolle: W.E.J. Tjeenk Willink.
- VAN STRIJEN CR (2009) Wet op de Lijkbezorging. Deventer: Kluwer Nederlandse staatswetten : editie Schuurman & Jordens.
- WIJBENGA BS, KONING RH, KOOISTRA-ASKE BJ, BOLT S, KUKS JBM, VAN ZANTEN-TIMMER G, VEENING JG, GERRITS PO (2010) 'Last-minute' donations influence actuarial prediction in an anatomical body donation program. *Ann Anat*, 192: 2-6.
- WORLD MEDICAL ASSOCIATION (2008) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, revised 2008.